

MISSISSIPPI STATE BOARD OF HEALTH

PART 5.0 REGULATION

GOVERNING THE PRODUCTION AND SALE OF MILK AND MILK PRODUCTS

5.1 Authority of Regulation

Section 41-3-15, (5) (a) and (ix), Mississippi Code of 1972, Annotated, gives the Mississippi State Board of Health (MSBH) the authority, in its discretion, to establish programs to promote public health in Milk Sanitation. Section 41-3-17 gives the MSBH "Power to make and publish rules and regulations".

5.2 Adoption by Reference

The current revision of the "Grade A Pasteurized Milk Ordinance", including all public health reasons, administrative procedures, and all appendices, recommended by the U. S. Public Health Service/Food and Drug Administration (hereinafter referred to as the "Milk Ordinance") is adopted by reference. Copies of this Regulation including the adopted Milk Ordinance may be obtained from the Dairy Farm Inspection Branch and/or the Milk Plant Inspection Branch.

5.3 Modifications of the Adoption by Reference

- (A) The provisions of this Regulation make amendments, additions, and deletions to the Milk Ordinance adopted by reference in Section 5.2 of this Regulation.
- (B) In the Milk Ordinance, several blank spaces are identified by three periods ("..."). The following provisions identify the location of the blank spaces in the Milk Ordinance and provide the words to be inserted in the blanks:
 - (1) On page 31, Part II, the second paragraph, the word "State" is inserted in the first blank, and the word "Mississippi" is inserted in the second blank.
 - (2) On page 36, Section 1, Item X, the words "delegated representative" are inserted in the first blank, and the words "Mississippi State Department of Health" are inserted in the second blank, and the rest of the sentence is deleted.
 - (3) On page 37, Section 2, the first paragraph, the word "State" is inserted in the first blank, and the word "Mississippi" is inserted in the second blank.
 - (4) On page 38, Section 3, the first paragraph, the word "State" is inserted in the first and third blanks, and the word "Mississippi" is inserted in the second and fourth blanks.

- (5) On page 42, Section 5, the first paragraph, the word "State" is inserted in the first blank, and the word "Mississippi" is inserted in the second blank.
 - (6) On page 46, Section 6, the last paragraph, the word "latest" is inserted in both blanks.
 - (7) On page 76, Section 7, Item 6p, the first paragraph, the word "State" is inserted in the first blank, and the word "Mississippi" is inserted in the second paragraph.
 - (8) On page 77, Section 7, Item 6p, Administrative Procedure #1, the word "State" is inserted in the first blank, and the word "Mississippi" is inserted in the second blank.
 - (9) On page 112, Section 11, the first paragraph, the word "State" is inserted in the first blank, and the word "Mississippi" is inserted in the second and third blanks.
- (C) The Milk Ordinance is amended by:
- (1) Deleting the words "or its jurisdiction" wherever the words appear in the Milk Ordinance, and substitute the words "Health Authority" for the words "Regulatory Agency" wherever the words appear in the Milk Ordinance.
 - (2) Deleting the words "twelve months from the date this ordinance is adopted" as they appear on page 121, Section 9, Milk and Milk Products Which May Be Sold, of the Milk Ordinance, and substitute the words "the effective date of this Ordinance".
 - (3) Adding the following Definitions to Section 1:
 - (a) Imitation Milk or Imitation Milk Products.
- Imitation milk or imitation milk products shall be taken to mean any substance, mixture, or compound in part or whole regardless of the name under which it may be processed, packaged, or sold or offered for sale in imitation or having the appearance or semblance of milk or milk products and which may or may not contain any milk or milk products. Imitation milk and milk products shall contain the minimum percentages of wholesome fat or oil other than milkfat and solids not fat as defined in this Regulation for milk and milk products. Where the words "milk" and/or "milk products" appear in this Regulation, they shall be interpreted to include "imitation milk" and/or "imitation milk products". Except that, substances, mixtures, or compounds having the appearance or semblance of milk or milk products that are prominently and conspicuously labeled as NON-DAIRY-PRODUCTS and which contain no amount of any major milk constituent shall not be defined as imitation milk or imitation milk products and are exempt from the requirements of this Regulation. NON-DAIRY-PRODUCTS may contain very small amounts of milk constituent derivatives added for functional purposes.

(b) Breed Milk.

Breed milk is milk produced from dairy farms milking exclusively one recognized breed of dairy cows, and complying with the definition of "milk".

(c) Sour Cream Dressing.

Sour cream dressing is made in semblance of sour cream and contains not less than 18 percent milkfat; except, that when the product is characterized by the addition of nutritive sweetener or bulky flavoring ingredients, the weight of the milkfat is not less than 18 percent of the remainder obtained by subtracting the weight of such optional ingredients from the weight of the product; but, in no case does the product contain less than 14.4 percent milkfat. Sour cream dressing has a titratable acidity of not less than one-half (0.5%) percent calculated as lactic acid. The blend of all ingredients used shall be pasteurized; except, that volatile flavoring substances, enzymes, bacterial cultures, and acidifying agents may be added following pasteurization.

(d) Cottage Cheese.

Cottage cheese is the soft uncured cheese which is prepared by mixing cottage cheese dry curd with a creaming mixture of safe and suitable ingredients and containing by weight not less than four (4%) percent milkfat and not more than 80 percent moisture. This product is further defined in the Code of Federal Regulations, Title 21, Section 133.128.

(e) Lowfat Cottage Cheese.

Lowfat cottage cheese is the soft uncured cottage cheese prepared by mixing cottage cheese dry curd with a creaming mixture of safe and suitable ingredients and containing by weight not less than one-half (0.5%) percent milkfat and not more than two (2%) percent milkfat and not more than 82.5 percent moisture. This product is further defined in the Code of Federal Regulations, Title 21, Section 133.131.

(f) Cottage Cheese Dry Curd or Dry Curd Cottage Cheese.

Cottage cheese dry curd or dry curd cottage cheese is the soft uncured cheese prepared by mixing cottage cheese dry curd with a creaming mixture of safe and suitable ingredients and containing by weight less than one-half (0.5%) percent milkfat and not more than 80 percent moisture. This product is further defined in the Code of Federal Regulations, Title 21, Section 133.129.

(4) Making the following changes in Section 3, Permits:

- (a) After the first paragraph on page 38, add the following paragraphs:

Dairy farms, milk haulers, transfer stations, and receiving stations shall obtain annual permits. When such permits expire, but were in good standing prior to expiration, an application for permit will not be required, and the health authority shall issue the annual permit. When such permits expire, but were not in good standing prior to expiration (the permitting inspection revealed a violation or violations), an application for a permit shall be made to the Health Authority upon forms provided by the Health Authority and shall contain such information as the Health Authority may require. In compliance with Mississippi Law, there shall be no fee charged for such permits.

Milk plants including milk and milk product processing plants, imitation milk and imitation milk product processing plants, and single-service container and closure (for milk and milk products and imitation milk and imitation milk products) fabricating plants shall obtain annual permits. An application for a permit shall be made to the Health Authority upon forms provided by the Health Authority and shall contain such information as the Health Authority may require. Each application for a permit shall be accompanied by a permit fee in the amount set forth in Mississippi Law payable to the Mississippi State Department of Health. Failure to submit fee on initial application shall result in disapproval of application. Failure to submit fee with subsequent annual application shall result in revoking the permit. When the Health Authority is in receipt of all required information and the permit fee, the annual permit shall be issued.

- (b) Insert the following italicized phrase shown below into the same sentence of the third paragraph on page 38:

.....imminent hazard to the public health; or whenever adulterated or misbranded milk and milk products are found; or in any case of a willful refusal.....

- (c) Delete the last paragraph of Administrative Procedures under Suspension of Permit on page 39.
- (d) Substitute the following paragraph for the first and second paragraphs under Reinstatement of Permits - Administrative Procedures on page 39.

Any milk producer, milk hauler, or milk plant, receiving station, or transfer station operator whose permit has been suspended may make written application for the reinstatement of his/her permit. Within one (1) week or less of the receipt of notification of any person whose permit has been suspended, the Health Authority shall make such inspections(s) and/or take sample(s) as deemed necessary to

determine compliance with the requirements of this Regulation, in accordance with Sections 5, 6, and 7 of the Milk Ordinance.

(5) Making the following change in Section 4, Labeling:

(a) Amend #1. labeling requirement on page 40 as follows:

1. The words "Grade A"; except, in the case of imitation milk and imitation milk products.

(6) Making the following changes in Section 5, Inspection of Dairy Farms and Milk Plants:

(a) Delete the entire paragraph and title concerning Certified Industry Inspection Program under the Administrative Procedures on page 44.

(b) Change the first sentence of the paragraph under Inspection Reports of the Administrative Procedures on page 45 as written below:

A copy of the inspection report shall be filed by the regulatory agency and retained for at least 24 months.

(7) Making the following changes in Section 6, the Examination of Milk and Milk Products:

(a) Insert the italicized phrase shown below into the same sentence of the fifth paragraph on page 45:

.....During any consecutive six months, at least four samples of pasteurized milk, *ultra-pasteurized, and aseptically processed milk*, flavored milk, flavored lowfat milk, flavored skim milk,.....

(b) Delete the italicized phrase shown below from the fifth paragraph on page 45:

.....flavored skim milk, each fat level of lowfat milk and each milk product defined in this Ordinance, *except aseptically processed*, shall be collected in at least four separate months,.....

(c) Insert the italicized sentence below into the sixth paragraph on page 45:

....Samples of milk and milk products shall be taken while in the possession of the producer or distributor at any time prior to delivery to the store or consumer. *Samples may be collected by the Health Authority from "drop shipments" of*

packaged milk and milk products after such products have been delivered to the cooler of a retail establishment by a distributor and are no longer in the possession of the distributor. Samples of milk and milk products from dairy retail stores, food service establishments, grocery stores, and other places where milk and milk products are sold shall be examined periodically as determined by the Health Authority.....

- (d) Amend the first paragraph on page 46 to read as follows by adding the italicized wording as shown below:

Required bacterial counts, somatic cell counts, cooling temperature checks, *and such other tests deemed necessary* shall be performed on raw milk for pasteurization. In addition, drug tests on producer's milk shall be conducted at least four times during any consecutive 6 months. Required bacterial counts, *test for milkfat content*, coliform determination, drug test, phosphatase test, *adulterant test*, cooling temperature check, *and such other tests deemed necessary* shall be performed on pasteurized milk, ultra-pasteurized, and aseptically processed milk and milk products as applicable.

- (e) Insert the italicized words shown below into the same sentence of the second paragraph on page 46.

.....Whenever two of the last four consecutive bacterial counts (except those for aseptically processed milk and milk products), *milkfat tests*, somatic cell counts, coliform determinations, or cooling temperatures, taken on separate days,.....

.....instituted whenever the standard is violated by three of the last five bacterial counts (except those for aseptically processed milk and milk products), *milkfat tests*, coliform determinations, cooling temperatures or somatic cell counts.

- (f) Insert the following paragraph between the second and third paragraphs on page 46:

Whenever a freezing point determination exceeds the standard, the cause shall be determined. Where the cause is added water, it shall be corrected and any milk or milk product involved shall not be offered for sale.

- (g) Insert the following paragraph between the fifth and sixth paragraphs on page 46:

The suspension of permit shall be rescinded when the results of the last sample comply with applicable standards. However, when the permit is suspended within six (6) months of the last suspension, it will be reinstated when the results of three (3) of the

last five (5) samples comply with applicable standards. Samples shall be taken at a rate of not more than two (2) per week. No milk produced on a dairy farm while under permit suspension shall be sold Grade A.

- (8) Adding provisions promulgated concerning "Equivalent Penalty" immediately after the Paragraph on Penalties of Appendix "N"; Part II, Regulatory Agency Responsibilities; Part B, Enforcement, on page 315 that are required by the "Grade A Pasteurized Milk Ordinance" to be developed and enforced by the Mississippi State Department of Health as follows:

Equivalent Penalties. The Health Authority shall use equivalent penalties where their use is allowed in Appendix "N". Provided; all milk used as equivalent penalty has been dumped to waste, and the dairy farmer whose Grade A permit has been suspended due to drug residual has not been paid for the milk dumped to waste nor has benefited financially for the milk dumped to waste. The weight of milk or the number of milkings proposed as equivalent penalty against the suspension period may include: (1) the dairy farmer's production found to be adulterated that is contributed to a tanker load that is also found to be adulterated; (2) the remaining weight of milk on the same adulterated tanker load of milk that was paid for by the dairy farmer whose Grade A permit was suspended; and/or, (3) milk in the dairy farmer's bulk milk tank(s) at the time of suspension of permit, due to positive drug residual, that is dumped to waste on the farm. Equivalent penalty cannot be "saved" and applied to a future permit suspension. The Health Authority shall request evidence in the form of information by telephone and documentation from the dairy farmer and/or management of the member dairy farmer's bulk tank unit concerning certification of the weight of milk or number of milkings dumped to waste. Financial instruments indicating payment or non-payment to the suspended dairy farmer for milk dumped to waste and indicating payment by the suspended dairy farmer for other milk on the adulterated tanker load of milk that was dumped to waste due to drug residual shall be provided the Health Authority upon request. If at any time and for any reason the Health Authority cannot obtain the evidence required above, an equivalent penalty counted against the suspension period will not be allowed when dealing with a suspended dairy farmer belonging to the non-cooperating bulk tank unit; and, the penalty will be the dumping of milk on the farm for the suspension period from that time forward.

- (9) Amending Table 1., Chemical, Bacteriological, And Temperature Standards, in Section 7 on page 51 as follows:
 - (a) Insert the following standards after "Somatic Cell Count" in the "Grade A Raw Milk And Milk Products For Pasteurization, Ultra-Pasteurization, Or Aseptic Processing" Section of the Table:

Freezing Point - 0.530 Degrees C. or Lower.

Pesticides and Other
Deleterious Chemicals Federal Food and Drug Administration
and Mississippi State Department of Health
Tolerances and Safe Levels.

- (b) Insert the following standards after "Drugs" in the "Grade A Pasteurized Milk And Bulk Shipped Heat-Treated Milk Products" Section of the Table:

Freezing Point - 0.525 Degrees C. or Lower.

Pesticides and Other
Deleterious Chemicals Federal Food and Drug Administration
and Mississippi State Department of Health
Tolerances and Safe Levels.

Milkfat Content As required by Product Definition herein.

- (c) Insert the following standards after "Drugs" in the "Grade A Aseptically Processed Milk And Milk Products" Section of the Table:

Freezing Point - 0.525 Degrees C. or Lower.

Pesticides and Other
Deleterious Chemicals Federal Food and Drug Administration and
Mississippi State Department of Health
Tolerances and Safe Levels.

Milkfat Content As required by Product Definition herein.

- (10) Making the following changes in the "Sanitation Requirements for Grade A Pasteurized, Ultra-Pasteurized and Aseptically Processed Milk and Milk Products" in Section 7, Standards for Milk and Milk Products, starting on page 73:

- (a) Insert the italicized phrase shown below into the same sentence of the first paragraph under Item 1p., Floors--Construction, on page 73.

.....sloped, provided with trapped drains *at least four (4) inches in diameter* and kept in good repair.....

- (b) Substitute the following paragraphs as appropriate for the first paragraph and Administrative Procedures 1 and 2 under Item 2p on page 74.

Walls and ceilings of rooms in which milk or milk products are handled, processed, or stored, or in which milk containers, utensils, and equipment are washed, and of all rooms in which the functional purpose may require cleaning with water and or chemicals, shall have a smooth, washable, light-colored surface, in good repair, equivalent to glazed tile, and not less than ten (10) feet in height.

Administrative Procedures

This item is deemed satisfied when:

1. Walls of all rooms in which milk is handled, processed or stored, or in which milk containers, utensils, or cases are washed, and of all rooms in which the functional purpose may require cleaning with water and/or chemicals, such as mechanical rooms, clean-in-place operations room, tank gallery, and refrigerated rooms, are constructed of sheet metal, dairy type tile, cement block, brick, concrete, cement plaster, or similar impervious materials of light color and smooth, washable surface.
2. Walls of other rooms and ceilings of all rooms are finished with smooth, washable, light-colored painted wood, tile, smooth-surface concrete, cement plaster, brick, or other equivalent materials with washable, light-colored surfaces.

- (c) Insert the following into Item 5p., Separate Rooms, following Sub-item #4 on page 75.

5. Cold storage.
6. Dry storage of ingredients and containers and packaging materials; and,
7. For mechanical purposes.

Plants receiving milk in bulk transport tanks shall provide for unloading, cleaning, and sanitizing facilities. Unless all milk and milk products are received in bulk transport tanks, a receiving room, mentioned in four (4) above shall be required.

Insert the following into Item 5p., Separate Rooms, following the second paragraph of the Item on page 75:

Cottage cheese vats shall be located in a separate room, maintained free from flies and other vermin, and kept in a clean condition: provided, that in existing installations, cottage cheese vats may be located in the processing room when there is no evidence

of overcrowding, excessive traffic, condensation, or splash. Cottage cheese vats located in processing rooms shall be equipped with multiple-service or single-service covers which shall be kept in place at all times during the "setting" operation.

Insert the following into the Administrative Procedures of Item 5p., Separate Rooms, following Administrative Procedure #7 on page 76:

8. Cottage cheese vats are located in a separate room, maintained free from flies and other vermin, and kept in a clean condition: provided, that in existing installations, cottage cheese vats may be located in the processing room when there is no evidence of overcrowding, excessive traffic, condensation, or splash.

9. Cottage cheese vats located in processing rooms are equipped with multiple-service or single-service covers which are kept in place at all times during the "setting" operation.

(d) Substitute the following paragraph for the first paragraph under Item 6p., Toilet-Sewage Disposal Facilities, on page 76:

Every milk plant shall be provided with flush type toilet facilities conforming with the Regulations of the State of Mississippi. Toilet rooms shall not open directly into any room in which milk and/or milk products are handled or processed. Toilet rooms shall be completely enclosed and shall have tight-fitting, self-closing doors. Toilet rooms shall have a lavatory including hot and cold running water, soap, and individual sanitary towels. Dressing rooms, toilet rooms, and fixtures shall be kept in a clean condition, in good repair, and shall be well-ventilated and well-lighted. Signs shall be posted in all toilet rooms used by employees directing them to wash their hands before returning to work. Sewage and other liquid wastes shall be disposed of in a sanitary manner approved by the Health Authority.

Add the following to the Administrative Procedures of Item 6p., Toilet-Sewage Disposal Facilities, after Administrative Procedure #8 on page 77:

9. Toilet rooms are supplied with a hand-washing lavatory including hot and cold running water, soap, and individual sanitary towels.

10. Signs are posted in all toilet rooms used by employees directing them to wash their hands before returning to work.

11. All drains from a flush type toilet room shall be trapped and drain into the sanitary sewer including floor drains, showers, lavatories, and all toilet room fixtures.

12. All wastes resulting from the cleaning and rinsing of containers, equipment, and floors, from flush toilets, and from washing facilities are disposed of in a sanitary manner by proper connection of the plant's sewer system to a public sewer; provided, if a public sewer is not available, a proper connection shall be made to a properly designed, installed, and operated individual wastewater disposal system approved by the Mississippi State Department of Environmental Quality.

13. All new sanitary toilet facilities serving plant processing facilities have floors constructed of dairy type tile, concrete, or similar impervious material sloped to drain; and, are provided with a trapped drain of at least two (2) inches in diameter draining into the sanitary sewer. The joints between the floor and walls are impervious; and, the floor and joint are maintained in good repair.

14. All new sanitary toilet facilities serving plant processing facilities have walls constructed of dairy type glazed tile, cement block, concrete, brick, or similar impervious, light-colored, smooth surfaced and washable material. The walls are maintained in good repair; and, the ceiling and painted surfaces are repainted when the finish discolors.

(e) Add the following to the Administrative Procedures of Item 7p., Water Supply, after Administrative Procedure #8 on page 78:

9. Water supply outlets are provided immediately available to the cottage cheese vats. The hose for transport of water for washing cottage cheese curd shall be arranged in such a way as to preclude the possibility of the hose touching the floor or the product.

(f) Amend Administrative Procedure #6 of Item 10p., Sanitary Piping, on page 81 by adding a second sentence to the paragraph as follows:

Provided, that cottage cheese, cheese dressings, or cheese ingredients may be transported by other methods which protect the product from contamination.

(g) Insert the italicized phrases shown below into the same sentence of the first paragraph under Item 11p., Construction and Repair of Containers and Equipment, on page 81:

.....shall be constructed for ease of cleaning; shall be kept in good repair; *shall meet the 3-A Sanitary Standards, and be approved by the State Health Authority. All equipment and appurtenances shall be at least two (2) feet from the wall and other stationary equipment; and adequate work space shall be provided.* All single-service containers, closures, gaskets, and other articles with.....

Add the following to the Administrative Procedures of Item 11p.,

Construction and Repair of Containers and Equipment, after Administrative Procedure #10 on page 82:

11. Woven wire screens or multiple screen packs used in fill nozzles to minimize the generation of foam in containers are designed, constructed, and installed in compliance with 3-A Sanitary Standards.

- (h) Insert the italicized sentences shown below into the same sentences of the first paragraph of Item 15p., Protection From Contamination, on page 87:

.....The processing or handling of products other than milk or milk products in the pasteurization plant shall be performed to preclude the contamination of such milk and milk products. *Breed milk and imitation milk and milk products as defined under Section 1 may be handled, processed, and packaged in a plant with other milk; provided, they are kept separate, and sufficient records maintained as directed by the State Health Authority. No ungraded milk and/or milk products are permitted in a plant; except, as provided under Section 2, Section 4, Item (1), and Section 9.* The storage, handling and use of poisonous or toxic materials shall be performed to preclude the contamination of milk and milk products, or ingredients of such milk and milk products or the product-contact -surfaces of all equipment, containers or utensils.

- (i) Insert the italicized sentence shown below into the same sentences of the first paragraph of Item 17p., Cooling of Milk, on page 114:

.....Every room or tank in which milk or milk products are stored shall be equipped with an accurate thermometer. *Open type surface coolers are prohibited.* Provided, that aseptically processed milk and milk products to be packaged in hermetically sealed containers shall be exempt from the cooling requirements of this item.

Substitute the following sentence for all paragraphs of Administrative Procedure #4 under Item 17p., Cooling of Milk, on pages 114 and 115.

4. All open type surface coolers are prohibited.

Amend the first paragraph of Administrative Procedure #3 under Item 17p., Cooling of Milk, on page 114 by adding the following sentence to the first paragraph:

Each delivery vehicle shall be equipped with an accurate thermometer.

- (j) Amend the first paragraph under Item 18p., Bottling and Packaging, on page 11 by adding the following sentence:

Provided, that cottage cheese, dry curd cottage cheese, and lowfat cottage cheese may be transported in sealed containers in a protected, sanitary manner from one plant to another for creaming and/or packaging.

Amend the Administrative Procedures under Item 18p., Bottling and Packaging, by adding a new Administrative Procedure on page 116 as follows:

13. Cottage cheese, dry curd cottage cheese, and lowfat cottage cheese are protected in a sanitary manner; they may be transported in sealed containers from one plant to another for creaming and/or packaging.

(k) Amend the Administrative Procedures under Item 19p., Capping, by adding to the end of each indicated Administrative Procedure on page 117 the appropriate sentence written below:

1. Provided further, that if suitable equipment is not available for capping cottage cheese, dry curd cottage cheese and lowfat cottage cheese, other methods of capping which eliminate possible chances of contamination may be approved by the Health Authority.

4. Closures for cottage cheese, dry curd cottage cheese and lowfat cottage cheese containers shall extend over the top edges of the container so as to protect the product from contamination during subsequent handling.

5. Provided, that this requirement shall not apply to cottage cheese, dry curd cottage cheese, and lowfat cottage cheese container closures, when such closures are supplied in a totally enclosed package, or wrapped so as to protect the closures.

(11) Making the following changes in Section 11, Milk and Milk Products From Points Beyond the Limits of Routine Inspection:

(a) Add to the Administrative Procedures on page 123 as follows:

7. After receipt, aseptically processed milk and milk products shall comply with the bacteriological and chemical requirements of Section 7.

8. All milk and milk products that are proposed for sale in the State of Mississippi shall comply with the labeling requirements of Section 4 upon receipt.

(12) Making the following change in Section 15, Enforcement:

(a) Substitute the following paragraph for the only paragraph under Section 15

on page 126:

This Regulation shall be enforced by the Health Authority in accordance with the Grade A Pasteurized Milk Ordinance with Administrative Procedures - 1993 Recommendations of the United States Public Health Service/Food and Drug Administration and its subsequent amended editions, a certified copy of which shall be on file in the Office of the Executive Secretary, Mississippi State Board of Health. Where the mandatory compliance with provisions of the appendices is specified, such provisions shall be deemed a requirement of the Regulation.

(13) Making the following change in Section 16, Penalty:

(a) Substitute the following paragraph for the only paragraph under Section 16 on page 126:

Any person who shall violate any of the provisions of this Regulation shall be guilty of a misdemeanor and, upon conviction thereof, shall be punished by a fine as provided by law, at the discretion of the Court and/or such persons may be enjoined from continuing such violations. Each day upon which such a violation occurs shall constitute a separate violation.

(14) Making the following change in Section 17, Repeal and Date of Effect:

(a) Substitute the following paragraph for the only paragraph under Section 17 on page 126:

All Regulations and parts of Regulations in conflict with this Regulation are hereby repealed. This Regulation shall be in full force and effective immediately upon adoption as provided by law.

(15) Adding a paragraph concerning :

CERTIFICATION OF REGULATION

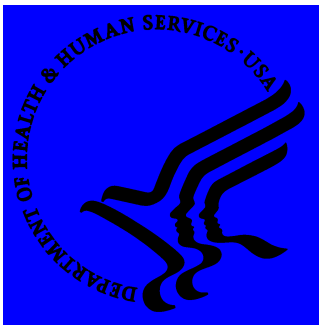
**THIS IS TO CERTIFY THAT THE ABOVE REGULATION GOVERNING
THE PRODUCTION AND SALE OF MILK AND MILK PRODUCTS WAS
ADOPTED BY THE MISSISSIPPI STATE BOARD OF HEALTH ON**

_____.

SECRETARY AND EXECUTIVE OFFICER

Grade “A” Pasteurized Milk Ordinance

1999 Revision



U.S. Department of Health and Human Services

Public Health Service

Food and Drug Administration

LIST OF PREVIOUS EDITIONS OF MILK ORDINANCE RECOMMENDED BY THE UNITED STATES PUBLIC HEALTH SERVICE/FOOD AND DRUG ADMINISTRATION

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1924. *Ordinance* only. Reprint No. 971 from *Public Health Reports* of November 7, 1924.
1926. *Ordinance* only. Reprint No. 1099 from *Public Health Reports* of July 30, 1926.
1927. *Ordinance and Code*. Mimeographed tentative draft, November 1927.
1929. *Ordinance and Code*. Mimeographed, July 1929.
1929. *Ordinance and Code*. Mimeographed, September 1929.
1931. *Ordinance and Code*. Mimeographed, September 1931.
1933. *Ordinance* only. Mimeographed, July 1933.
1933. *Ordinance and Code*. Mimeographed, July 1933.
1933. *Ordinance* only. Rotoprinted, December 1933.
1933. *Ordinance and Code*. Rotoprinted, December 1933.
1934. *Ordinance and Code*. Rotoprinted, August 1934.
1934. *Ordinance* only. Rotoprinted, August 1934.
1935. *Ordinance and Code*. Printed as *Public Health Bulletin No. 220*, 1935 edition, July 1935.
1936. *Ordinance* only. Mimeographed, December 1936.
1936. *Ordinance and Code*. Printed as *Public Health Bulletin No. 220*, 1936 edition, January 1937.
1939. *Ordinance and Code*. Mimeographed, January 1939.
1939. *Ordinance* only. Mimeographed, February 1939.
1939. *Ordinance* only. Mimeographed, November 1939.
1939. *Ordinance and Code*. Printed as *Public Health Bulletin No. 220*, 1939 edition, February 1940.
1947. *Ordinance* only. Mimeographed tentative draft, August 1947.
1949. *Ordinance* only. Multithed, April 1949.
1951. *Ordinance* only. Multithed, November 1951.
1953. *Ordinance and Code*. Printed as *Public Health Service Publication No. 229*.
1965. *Pasteurized Milk Ordinance*. *Public Health Service Publication No. 229*.
1978. *Pasteurized Milk Ordinance*. *Public Health Service/Food and Drug Administration Publication No. 229*.
1983. *Pasteurized Milk Ordinance*. *Public Health Service/Food and Drug Administration Publication No. 229*.
1985. *Pasteurized Milk Ordinance*. *Public Health Service/Food and Drug Administration Publication No. 229*.
1989. *Pasteurized Milk Ordinance*. *Public Health Service/Food and Drug Administration Publication No. 229*.
1993. *Pasteurized Milk Ordinance*. *Public Health Service/Food and Drug Administration Publication No. 229*.
1995. *Pasteurized Milk Ordinance*. *Public Health Service/Food and Drug Administration Publication No. 229*.
1997. *Pasteurized Milk Ordinance*. *Public Health Service/Food and Drug Administration Publication No. 229*.
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**PUBLIC HEALTH SERVICE/FOOD AND DRUG ADMINISTRATION
PUBLICATION NO. 229**

FOREWORD

The milk sanitation program of the United States Public Health Service is one of its oldest and most respected activities. The interest of the Public Health Service in milk sanitation stems from two important public health considerations. First, of all foods, none surpasses milk as a single source of those dietary elements needed for the maintenance of proper health, especially in children and older citizens. For this reason, the Service has for many years promoted increased milk consumption. Second, milk has a potential to serve as a vehicle of disease and has, in the past, been associated with disease outbreaks of major proportions.

The incidence of milkborne illness in the United States has been sharply reduced in recent years. In 1938, milkborne outbreaks constituted 25 percent of all disease outbreaks due to infected foods and contaminated water. Our most recent information reveals that milk and fluid milk products continue to be associated with less than 1 percent of such reported outbreaks. Many groups have contributed to this commendable achievement, including Public Health and Agricultural agencies, dairy and related industries, several interested professional groups, educational institutions and the consuming public. The Public Health Service is proud to have contributed to the protection and improvement of the milk supply of the nation through technical assistance, training, research, standards development, evaluation and certification activities.

Despite the progress that has been made, occasional milkborne outbreaks still occur, emphasizing the need for continued vigilance at every stage of production, processing, pasteurization and distribution of milk and milk products. During the past decade, problems associated with the sanitary control of milk and milk products have become extremely complex because of new products, new processes, new chemicals, new materials and new marketing patterns, which must be evaluated in terms of their public health significance. The *Grade "A" Pasteurized Milk Ordinance--1978 Recommendations of the United States Public Health Service/Food and Drug Administration, 1999 Revision* translates this new knowledge and technology into effective and practicable public health practices.

The responsibility for insuring the ready availability and safety of milk and milk products is not confined to an individual community or a State, or to the Federal Government, it is the concern of the entire nation. With the continued cooperation of all interested groups engaged in the sanitary control of milk and milk products, including Government and industry, such responsibility can be accepted with confidence.

PREFACE

Public Health Service activities in the area of milk sanitation began at the turn of the century with studies on the role of milk in the spread of disease. These studies led to the conclusion that effective public health control of milkborne disease requires the application of sanitation measures throughout the production, handling, pasteurization, and distribution of milk. These early studies were followed by research to identify and evaluate sanitary measures which might be used to control disease, including studies which led to improvement of the pasteurization process.

To assist States and municipalities in initiating and maintaining effective programs for the prevention of milkborne disease, the Public Health Service, in 1924, developed a model regulation, known as the *Standard Milk Ordinance* for voluntary adoption by State and local milk control agencies. To provide for the uniform interpretation of this *Ordinance*, an accompanying *Code* was published in 1927 which provided administrative and technical details as to satisfactory compliance. This model milk regulation, now titled the *Grade "A" Pasteurized Milk Ordinance*--1978 Recommendations of the United States Public Health Service/Food and Drug Administration, 1999 Revision, represents the 30th revision since 1924 and incorporates new knowledge into public health practice.

The *Grade "A" Pasteurized Milk Ordinance* was not produced by the Public Health Service/Food and Drug Administration alone. As with every preceding edition, it was developed with the assistance of milk sanitation and regulatory agencies at every level of Federal, State, and local government including both health and agriculture departments; all segments of the dairy industry including producers, plant operators, equipment manufacturers, and associations; many educational and research institutions; and with helpful comments from many individual sanitarians and others.

Public Health Service/Food and Drug Administration recommended *Grade "A" Pasteurized Milk Ordinance* is the basic standard used in the voluntary Cooperative State-PHS Program for Certification of Interstate Milk Shippers, a program participated in by all 50 States, the District of Columbia and U.S. Trust Territories. The National Conference on Interstate Milk Shipments (NCIMS) in accordance with the Memorandum of Understanding with the Food and Drug Administration, has at its biennial conferences in 1979, 1981, 1983, 1985, 1987, 1989, 1991, 1993, 1995, 1997 and 1999 recommended changes and modifications to the *Grade "A" Pasteurized Milk Ordinance*. These changes have been incorporated into this 1999 revision. The counsel and guidance rendered by the Conference in preparation of this edition of the *Grade "A" Pasteurized Milk Ordinance* is deeply appreciated.

The *Grade "A" Pasteurized Milk Ordinance* is incorporated by reference in Federal specifications for procurement of milk and milk products; is used as the sanitary regulation for milk and milk products served on interstate carriers; and is recognized by the public health agencies, the milk industry, and many others as a national standard for milk sanitation.

The *Grade "A" Pasteurized Milk Ordinance* adopted and uniformly applied, will continue to provide effective public health protection without being unduly burdensome to either regulatory agencies or the dairy industry. It represents a "grass-roots" consensus of current knowledge and experiences and as such represents a practical and equitable milk sanitation standard for the nation.

INTRODUCTION

The following *Grade "A" Pasteurized Milk Ordinance*, with Appendices, is recommended for legal adoption by States, counties, and municipalities, in order to encourage a greater uniformity and a higher level of excellence of milk sanitation practice in the United States. An important purpose of this recommended standard is to facilitate the shipment and acceptance of milk and milk products of high sanitary quality in interstate and intrastate commerce.

This edition of the *Ordinance* contains sanitary standards for *Grade "A"* pasteurized milk and milk products defined in Section 1 only.

The following form is suggested for adoption by States, municipalities, and counties subject to the approval of the appropriate legal authority. Adoption of this form will reduce the cost of publishing and printing, and will enable the *Grade "A" Pasteurized Milk Ordinance* to be easily kept current. The adoption of this form is considered legal in many States and has been so adopted. The Council of State Governments has prepared a model State law, *Milk and Food Codes Adoption-by-Reference Act*,¹ which is recommended for enactment by States to enable communities to adopt milk and food ordinances by reference.

An ordinance to regulate the production, transportation, processing, handling, sampling, examination, labeling, and sale of milk and milk products; the inspection of dairy herds, dairy farms, and milk plants; the issuing and revocation of permits to milk producers, haulers, and distributors; and the fixing of penalties.

The.....of.....² ordains:

SECTION 1. The production, transportation, processing, handling, sampling, examination, labeling and sale of all milk and milk products sold for the ultimate consumption within the² or its jurisdiction; the inspection of dairy herds, dairy farms and milk plants; and the issuing and revocation of permits to milk producers, haulers and distributors shall be regulated in accordance with the provisions of the current edition of the *Pasteurized Milk Ordinance*, a certified copy³ of which is filed in the office of the appropriate official. *Provided*, that Sections 15 and 16 of said ordinance shall be replaced, respectively by Sections 2 and 3 below.

SECTION 2. Any person who shall violate any of the provisions of this *Ordinance* shall be guilty of a misdemeanor and, upon conviction thereof, shall be punished by a fine of not more than \$....., and/or such persons may be enjoined from continuing such violations. Each day upon which such a violation occurs shall constitute a separate violation.

SECTION 3. All Ordinances and parts of ordinances in conflict with this *Ordinance*, shall be repealed 12 months after the adoption of this *Ordinance*, at which time this *Ordinance* shall be in full force and effect, as provided by law.

Legal Aspects: Recommendations concerning legal aspects have been suggested from time to time by the Office of the General Counsel and have been incorporated into the *Ordinance*. Other changes have also been incorporated on the advice of various State and local legal counsel.

¹ A copy of the model act is included in Suggested State Legislation Programs for 1950, developed by the Council of State Governments, Box 11910, Iron Works Pike, Lexington, KY 40578.

² Substitute proper legal jurisdiction here and in all similar places throughout the Ordinance.

³ A certified copy may be secured from the Department of Health and Human Services, Public Health Service, Food and Drug Administration(HFS-626), 200 C. Street, S.W., Washington, D.C. 20204.

The *Ordinance* has been widely adopted and used for many years and has been upheld by court actions. One of the most comprehensive decisions upholding the various provisions of the *Ordinance* was that of the District Court, Reno County, Kansas, in the case of *Billings et al. v. City of Hutchinson et al.*, decided May 1, 1934. In this action, the plaintiffs unsuccessfully sought to enjoin the enforcement of the Hutchinson ordinance on the grounds that (a) it was unreasonable; (b) it conflicted with State statutes; (c) the license fees provided in the local ordinance (but not in the *Ordinance* recommended by the Public Health Service) were in excess of expenses; and (d) the milk inspector was clothed with arbitrary powers. (Reprint No. 1629 from *Public Health Reports* of June 8, 1934.)

The model ordinance discourages the use of public health regulations to establish unwarranted trade barriers against the acceptance of high quality milk from other milksheds (Section 11). On repeated requests from the Association of State and Territorial Health Officers and the National Conference on Interstate Milk Shipments, the Public Health Service/Food and Drug Administration is actively cooperating in the voluntary program for the certification of interstate milk shippers. Such a program would be impossible without widespread agreement on uniform standards, such as those of the recommended *Ordinance*.

The value of these standards as a means of overcoming interstate trade barriers was recognized by the U.S. Supreme Court in the case of the *Dean Milk Company v. City of Madison*. (No. 258--October term, 1950). The Court reversed the decision of the Wisconsin Supreme Court which had sustained an ordinance requirement imposing a 5-mile limit on the location of pasteurization plants selling milk in Madison and pointed out that Madison consumers would be adequately safeguarded if the city relied upon the provisions of Section 11 of the Public Health Service's recommended *Milk Ordinance*.

The Public Health Service has no legal jurisdiction in the enforcement of milk sanitation standards, except on interstate carriers and milk and milk products shipped in interstate commerce. Elsewhere, it serves solely in an advisory and stimulative capacity. Its program is designed primarily to assist State and local regulatory agencies. Its aim is to promote the establishment of effective and well-balanced milk sanitation programs in each State; to stimulate the adoption of adequate and uniform State and local milk control legislation; and to encourage the application of uniform enforcement procedures through appropriate legal and educational measures.

When this *Ordinance* is adopted locally, its enforcement becomes a function of the local or State authorities. Consequently, the *Ordinance* should be adopted only if adequate provisions can be made for qualified personnel and for suitable laboratory facilities. Small municipalities which cannot afford to provide these services should arrange for supervision by the county or State health department, or seek cooperation with neighboring municipalities in organizing a milk-control district or area.

The charter and the legal counsel of the government unit involved should be consulted for information or advice on proper legal procedures, such as the recording and advertising of the *Ordinance* after passage.

Adoption: In the interest of national uniformity, it is recommended that no changes be made in this *Ordinance* when adopted by a State or local community, unless changes are necessary to avoid conflict with State law. Modifications should be contemplated with extreme caution so as not to render the *Ordinance* unenforceable. In order to promote uniformity, it is recommended that all of the administrative procedures be adopted as well.

Amendment of Existing Regulations: States and communities that have adopted the 1989 or earlier editions of the Public Health Service recommended milk sanitation ordinances are urged to bring such *Ordinance* up-to-date in order to take advantage of the most current developments in milk sanitation and administration. States and communities whose milk sanitation law or regulations are not based on past Public Health Service recommended milk sanitation ordinances are urged to consider the attendant public health benefits, as well as those economic in nature, which can accrue upon adoption and implementation of the *Grade "A" Pasteurized Milk Ordinance*.

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GRADE "A" PASTEURIZED MILK ORDINANCE - 1999 Revision

An ordinance defining "milk" and certain "milk products", "milk producer", "pasteurization", etc.; prohibiting the sale of adulterated and misbranded milk and milk products; requiring permits for the sale of milk and milk products; regulating the inspection of dairy farms and milk plants, the examination, labeling, pasteurization, aseptic processing and packaging and distribution and sale of milk and milk products; providing for the construction of future dairy farms and milk plants; and the enforcement of this *Ordinance* and the fixing of penalties.

Be it ordained by the ... of ...¹ as follows:

SECTION 1. DEFINITIONS

Terms used in this document not specifically defined herein are those within Title 21, Code of Federal Regulations and/or the *Federal Food, Drug, and Cosmetic Act* as amended.

The following additional definitions shall apply in the interpretation and the enforcement of this *Ordinance*:

A. BULK MILK HAULER/SAMPLER: A bulk milk hauler/sampler is any person who collects official samples and may transport raw milk from a farm and/or raw milk products to or from a milk plant, receiving station or transfer station and has in their possession a permit from any state to sample such products.

B. BULK MILK PICKUP TANKER: A bulk milk pickup tanker is a vehicle, including the truck, tank and those appurtenances necessary for its use, used by a bulk milk hauler/sampler to transport bulk raw milk for pasteurization from a dairy farm to a milk plant, receiving station, or transfer station.

C. CONCENTRATED MILK: Concentrated milk is a fluid product, unsterilized and unsweetened, resulting from the removal of a considerable portion of the water from the milk, which, when combined with potable water in accordance with instructions printed on the container, results in a product conforming with the milkfat and milk solids not fat levels of milk as defined in this section.

D. CONCENTRATED MILK PRODUCTS: Concentrated milk products shall be taken to mean and to include homogenized concentrated milk, concentrated nonfat milk, concentrated reduced fat or low fat milk, and similar concentrated products made from concentrated milk or concentrated non-fat milk, and which, when combined with potable water in accordance with instructions printed on the container, conform with the definitions of the corresponding milk products in this section.

E. DAIRY FARM: A dairy farm is any place or premises where one or more lactating animals (cows, goats or sheep) are kept, and from which a part or all of the milk or milk product(s) is provided, sold or offered for sale to a receiving station, transfer station or milk plant.

F. DAIRY PLANT SAMPLER: A person responsible for the collection of official samples for regulatory purposes

¹ Substitute proper legal jurisdiction here and in all similar places throughout the Ordinance.

outlined in Section 6 of the *Grade "A" Pasteurized Milk Ordinance*. This person is an employee of the regulatory agency and is evaluated at least once every two-year period by the State Sampling Surveillance Officer.

G. EGGNOG OR BOILED CUSTARD: Eggnog or boiled custard is the product defined in the *Code of Federal Regulations*, Title 21, Section 131.170.

H. FROZEN MILK CONCENTRATE: Frozen milk concentrate is a frozen milk product with a composition of milkfat and milk solids not fat in such proportions that when a given volume of concentrate is mixed with a given volume of water the reconstituted product conforms to the milkfat and milk solids not fat requirements of whole milk. In the manufacturing process, water may be used to adjust the primary concentrate to the final desired concentration. The adjusted primary concentrate is pasteurized, packaged, and immediately frozen. This product is stored, transported and sold in the frozen state.

I. GOAT MILK: Goat milk is the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one or more healthy goats. Goat milk sold in retail packages shall contain not less than 2.5 percent milkfat and not less than 7.5 percent milk solids not fat. Goat milk shall be produced according to the sanitary standards of this *Ordinance*. The word "milk" shall be interpreted to include goat milk.

J. GRADE "A" DRY MILK AND WHEY PRODUCTS: Grade "A" dry milk and whey products are products which have been produced for use in Grade "A" pasteurized or aseptically processed milk products and which have been manufactured

under the provisions of the most current revision of the *Grade "A" Condensed and Dry Milk Products and Condensed and Dry Whey--Supplement I to the Grade "A" Pasteurized Milk Ordinance*.

K. MILK DISTRIBUTOR: A milk distributor is any person who offers for sale or sells to another any milk or milk products.

L. MILK PLANT: A milk plant is any place, premises or establishment where milk or milk products are collected, handled, processed, stored, pasteurized, aseptically processed, packaged, or prepared for distribution.

M. MILK PRODUCER: A milk producer is any person who operates a dairy farm and provides, sells or offers milk for sale to a milk plant, receiving station or transfer station.

N. MILK PRODUCTS: Milk products include cream, light cream, light whipping cream, heavy cream, heavy whipping cream, whipped cream, whipped light cream, sour cream, acidified sour cream, cultured sour cream, half-and-half, sour half-and-half, acidified sour half-and-half, cultured sour half-and-half, reconstituted or recombined milk and milk products, concentrated milk, concentrated milk products, nonfat (skim) milk, reduced fat or lowfat milk, frozen milk concentrate, eggnog, buttermilk, cultured milk, cultured reduced fat or lowfat milk, cultured nonfat (skim) milk, yogurt, lowfat yogurt, nonfat yogurt, acidified milk, acidified reduced fat or lowfat milk, acidified nonfat (skim) milk, low-sodium milk, low-sodium reduced fat or lowfat milk, low-sodium nonfat (skim) milk, lactose-reduced milk, lactose-reduced reduced fat or lowfat milk, lactose-reduced nonfat (skim) milk, aseptically processed

and packaged milk and milk products as defined in this section, milk, reduced fat or lowfat milk or nonfat (skim) milk with added safe and suitable microbial organisms and any other milk product made by the addition or subtraction of milkfat or addition of safe and suitable optional ingredients for protein, vitamin or mineral fortification of milk products defined herein.^{2,3}

Milk products also include those dairy foods made by modifying the federally standardized products listed in this Section in accordance with 21 CFR 130.10 - Requirements for foods named by use of a nutrient content claim and a standardized term.

This definition shall include those milk and milk products, as defined herein, which have been aseptically processed and then packaged.

Milk and milk products which have been retort processed after packaging or which have been concentrated, condensed or dried are included in this definition only if they are used as an ingredient to produce

² Communities and/or states desiring to regulate Cottage cheese and dry curd cottage cheese under the terms of this *Ordinance* should insert the following definitions:

Cottage Cheese – Cottage cheese is the product defined in the Code of Federal Regulations, Title 21 Section 133.128.

Dry Curd Cottage Cheese – Dry curd cottage cheese is the product defined in the Code of Federal Regulations, Title 21 Section 133.129.

³ Whey, caseinates, lactalbumin and other milk derived ingredients are required to be derived from a Grade “A” raw milk source.

any milk or milk product defined herein or if they are labeled as Grade “A” as described in section 4.

This definition is not intended to include dietary products (except as defined herein), infant formula, ice cream or other desserts, butter or cheese.

O. MILK TANK TRUCK: A milk tank truck is the term used to describe both a bulk milk pickup tanker and a milk transport tank.

P. MILK TANK TRUCK CLEANING FACILITY: Any place, premise, or establishment, separate from a milk plant, receiving or transfer station, where a milk tank truck is cleaned and sanitized.

Q. MILK TANK TRUCK DRIVER: A milk tank truck driver is any person who transports raw or pasteurized milk products to or from a milk plant, receiving station or transfer station. Any transportation of a direct farm pickup requires the milk tank truck driver to have responsibility for accompanying official samples.

R. MILK TRANSPORT TANK: A milk transport tank is a vehicle, including the truck and tank, used by a bulk milk hauler/sampler to transport bulk shipments of milk from a milk plant, receiving station or transfer station to another milk plant, receiving station or transfer station.

S. MILK TRANSPORTATION COMPANY: A milk transportation company is the person responsible for a milk tank truck(s).

T. OFFICIAL LABORATORY: An official laboratory is a biological, chemical or physical laboratory which is under the

direct supervision of the State or a local regulatory agency.

U. OFFICIALLY DESIGNATED LABORATORY: An officially designated laboratory is a commercial laboratory authorized to do official work by the regulatory agency, or a milk industry laboratory officially designated by the regulatory agency for the examination of producer samples of Grade "A" raw milk for pasteurization and commingled milk tank truck samples of raw milk for drug residues and bacterial limits.

V. PASTEURIZATION: The terms "pasteurization", "pasteurized" and similar terms shall mean the process of heating every particle of milk or milk product, in properly designed and operated equipment, to one of the temperatures given in the following chart and held continuously at or above that temperature for at least the corresponding specified time:

Temperature	Time
*63°C (145°F)	30 minutes
*72°C (161°F)	15 seconds
89°C (191°F)	1.0 second
90°C (194°F)	0.5 second
94°C (201°F)	0.1 second
96°C (204°F)	0.05 second
100°C (212°F)	0.01 second
*If the fat content of the milk product is 10 percent or more, or if it contains added sweeteners, the specified temperature shall be increased by 3°C (5°F). <i>Provided</i> , that eggnog shall be heated to at least the following temperature and time specifications:	
69°C (155°F)	30 minutes
80°C (175°F)	25 seconds
83°C (180°F)	15 seconds

Provided further, that nothing shall be construed as barring any other pasteurization process which has been recognized by the Food and Drug Administration to be equally efficient and which is approved by the regulatory agency.

W. PERSON: The word "person" shall include any individual, plant operator, partnership, corporation, company, firm, trustee, association or institution.

X. RECEIVING STATION: A receiving station is any place, premises or establishment where raw milk is received, collected, handled, stored or cooled and prepared for further transporting.

Y. RECONSTITUTED OR RECOMBINED MILK AND MILK PRODUCTS: Reconstituted or recombined milk and/or milk products shall mean milk or milk products defined in this section which result from reconstituting or recombining of milk constituents with potable water when appropriate.⁴

Z. REGULATORY AGENCY: The regulatory agency shall mean the ... of the ...⁵ or his authorized representative. The term, "regulatory agency", whenever it appears in the *Ordinance* shall mean the appropriate agency having jurisdiction and control over the matters embraced within this *Ordinance*.

⁴ Where State law does not permit the sale of reconstituted or recombined milk and/or milk products, Definition Y and other corresponding references should be omitted.

⁵ Substitute proper legal jurisdiction here and in all similar places throughout the *Ordinance*.

AA. **SHEEP MILK:** Sheep milk is the normal lacteal secretion practically free of colostrum, obtained by the complete milking of one or more healthy sheep. Sheep milk shall be produced according to the sanitary standards of this *Ordinance*. The word "milk" shall be interpreted to include sheep milk.

BB. **TRANSFER STATION:** A transfer station is any place, premises or establishment where milk or milk products are transferred directly from one milk tank truck to another.

SECTION 2. ADULTERATED OR MISBRANDED MILK OR MILK PRODUCTS

No person shall, within the ... of ...⁶., or its jurisdiction, produce, provide, sell, offer, or expose for sale or have in possession with intent to sell any milk or milk product which is adulterated or misbranded. *Provided*, that in an emergency, the sale of pasteurized milk and milk products which do not fully meet the requirements of this *Ordinance*, may be authorized by the regulatory agency.

Any adulterated or misbranded milk or milk product may be impounded by the regulatory agency and disposed of in accordance with applicable laws or regulations.

ADMINISTRATIVE PROCEDURES

This section of the *Ordinance* shall be used in impounding the products of, or preferring charges against, persons who adulterate or misbrand their milk or milk

products, or label them with any grade designation not authorized by the regulatory agency under the terms of this *Ordinance* or who sell or deliver ungraded milk or milk products, except as may be permitted under this section in an emergency. An emergency is defined as a general and acute shortage in the milkshed, not simply one distributor's shortage.

SECTION 3. PERMITS

It shall be unlawful for any person who does not possess a permit from the regulatory agency of the ... of ... to bring into, send into or receive into the ... of ...⁷ or its jurisdiction, for sale, or to sell, or offer for sale therein or to have in storage any milk or milk products defined in this *Ordinance*. *Provided*, that grocery stores, restaurants, soda fountains and similar establishments where milk or milk products are served or sold at retail, but not processed, may be exempt from the requirements of this section.

Only a person who complies with the requirements of this *Ordinance* shall be entitled to receive and retain such a permit. Permits shall not be transferable with respect to persons and/or locations.

The regulatory agency shall suspend such permit, whenever it has reason to believe that a public health hazard exists; or whenever the permit holder has violated any of the requirements of this *Ordinance*; or whenever the permit holder has interfered with the regulatory agency in the performance of its duties. *Provided*, that the regulatory agency shall, in all cases except where the milk or milk product involved creates, or appears to create, an imminent

⁶ Substitute proper legal jurisdiction here and in all similar places throughout the *Ordinance*.

⁷ Substitute proper legal jurisdiction here and in all similar places throughout the *Ordinance*.

hazard to the public health; or in any case of a willful refusal to permit authorized inspection, serve upon the holder a written notice of intent to suspend permit, which notice shall specify with particularity the violation(s) in question and afford the holder such reasonable opportunity to correct such violation(s) as may be agreed to by the parties, or in the absence of agreement, fixed by the regulatory agency before making any order of suspension effective. A suspension of permit shall remain in effect until the violation(s) has been corrected to the satisfaction of the regulatory agency.

Upon notification, acceptable to the regulatory agency, by any person whose permit has been suspended, or upon application within 48 hours of any person who has been served with a notice of intention to suspend, and in the latter case before suspension, the regulatory agency shall within 72 hours proceed to a hearing to ascertain the facts of such violation(s) or interference and upon evidence presented at such hearing shall affirm, modify or rescind the suspension or intention to suspend.

Upon repeated violation(s), the regulatory agency may revoke such permit following reasonable notice to the permit holder and an opportunity for a hearing. This section is not intended to preclude the institution of court action as provided in Sections 5 and 6.

ADMINISTRATIVE PROCEDURES

ISSUANCE OF PERMITS: Every milk producer, milk distributor, bulk milk hauler/sampler, milk tank truck⁸, milk transportation company and each milk plant, receiving station, milk tank truck cleaning facility and transfer station operator shall

hold a valid permit. The permit for a milk tank truck or milk tank trucks may be issued to the milk transportation company. Milk producers who transport milk or milk products, only from their own dairy farms; employees of a milk distributor or milk plant operator who possesses a valid permit; and employees of a milk transportation company that possesses a valid permit and transports milk from a milk plant, receiving station or transfer station shall not be required to possess a bulk milk hauler/sampler's permit. Grocery stores, restaurants, soda fountains and similar establishments where milk and milk products are served or sold at retail, but not processed, may be exempt from the requirements of this section.

SUSPENSION OF PERMIT:

When any requirement(s) of this *Ordinance* is violated, the permit holder is subject to the suspension of his permit.

The regulatory agency may forego suspension of the permit, provided the product or products in violation are not sold or offered for sale as Grade "A" product. A regulatory agency may allow the imposition of a monetary penalty in lieu of a permit suspension, provided product or products in violation are not sold or offered for sale as Grade "A" product.

HEARINGS: If a State or municipal administrative procedure act, which provides procedures for administrative hearings and judicial review of administrative determinations, is available, the act shall be made applicable by reference to the hearings provided for in the *Ordinance*. If such administrative procedures act is not available, appropriate procedures, including provision for notice, hearing officer, his authority, record of hearing, rules of evidence and court review shall be established by appropriate authority.

⁸ The permit for a milk tank truck may be issued to the responsible person for the milk tank truck(s).

REINSTATEMENT OF PERMITS: Any producer, distributor, bulk milk hauler/sampler, milk transportation company or plant operator whose permit has been suspended may make written application for the reinstatement of his permit.

When the permit suspension has been due to a violation of any of the bacterial, coliform or cooling-temperature standards, the regulatory agency, within 1 week after the receipt of notification for reinstatement of permit, shall issue a temporary permit after determining by an inspection of the facilities and operating methods that the conditions responsible for the violation have been corrected. When a permit suspension has been due to a violation of the somatic cell count standard, the regulatory agency may issue a temporary permit whenever a resampling of the herd's milk supply indicates the milk supply to be within acceptable limits as prescribed in Section 7. Samples shall then be taken at the rate of not more than two per week on separate days within a 3-week period and the regulatory agency shall reinstate the permit upon compliance with the appropriate standard as determined in accordance with Section 6 of this *Ordinance*.

Whenever the permit suspension has been due to a violation of a requirement other than bacteriological, coliform, somatic cell count, drug residue test or cooling-temperature standards, the notification shall indicate that the violation(s) has been corrected. Within 1 week of the receipt of such notification, the regulatory agency shall make an inspection of the applicant's establishment, and as many additional inspections thereafter as are deemed necessary, to determine that the applicant's establishment is complying with the requirements. When the findings justify, the permit shall be reinstated.

When a permit suspension has been due to positive drug residues, the permit shall be reinstated in accordance with the provisions of Appendix N.

SECTION 4. LABELING

All bottles, containers and packages enclosing milk or milk products defined in Section 1 of this *Ordinance* shall be labeled in accordance with the applicable requirements of the *Federal Food, Drug, and Cosmetic Act as amended*, the *Nutrition Labeling and Education Act of 1990*, and regulations developed thereunder, the Code of Federal Regulations, and in addition, shall comply with applicable requirements of this section as follows:

All bottles, containers and packages enclosing milk or milk products, except milk tank trucks, storage tanks and cans of raw milk from individual dairy farms, shall be conspicuously marked with:

1. The identity of the plant where pasteurized, ultra-pasteurized or aseptically processed.
2. The words "keep refrigerated after opening" in the case of aseptically processed milk and milk products.
3. The word "Goat" or "Sheep" shall precede the name of the milk or milk product when the product is or is made from goat or sheep milk respectively.
4. The words "Grade "A"" on the exterior surface. Acceptable locations shall include the principal display panel, the secondary or informational panel, or the cap/cover.
5. The word "reconstituted" or "recombined" if the product is made by reconstitution or recombination.

All vehicles and milk tank trucks containing milk or milk products shall be

legibly marked with the name and address of the milk plant or hauler in possession of the contents.

Milk tank trucks transporting raw, heat-treated or pasteurized milk and milk products to a milk plant from another milk plant, receiving or transfer station are required to be marked with the name and address of the milk plant or hauler and shall be sealed; in addition, for each such shipment, a shipping statement shall be prepared containing at least the following information:

- a.) Shipper's name, address and permit number. Each milk tank truck load of milk shall include the IMS Bulk Tank Unit (BTU) identification number(s) or the IMS listed Plant Number (for farm groups listed with a plant) on the weight ticket or manifest.
- b.) Permit identification of hauler, if not an employee of the shipper.
- c.) Point of origin of shipment.
- d.) Tanker identification number.
- e.) Name of product.
- f.) Weight of product.
- g.) Temperature of product when loaded.
- h.) Date of shipment.
- i.) Name of supervising regulatory agency at the point of origin of shipment.
- j.) Whether the contents are raw, pasteurized, or in the case of cream, lowfat or skim milk, whether it has been heat treated.
- k.) Seal number on inlet, outlet, wash connections and vents.
- l.) Grade of product.

All cans of raw milk from individual dairy farms shall be identified by the name or number of the individual milk producer.

Each milk tank truck load of milk shall be accompanied by documentation (weigh ticket or manifest) which shall include the IMS BTU Identification Number(s) or the IMS Listed Plant Number (for farm groups listed with a plant).

ADMINISTRATIVE PROCEDURES

EMERGENCY SUPPLIES--

LABELING: When the sale of ungraded milk or milk products is authorized during emergencies, under the terms of Section 2, the label must bear the designation "ungraded". When such labeling is not available, the regulatory agency shall take immediate steps to inform the public that the particular supply is ungraded and that the supply will be properly labeled as soon as the distributor can obtain the required labels.

IDENTITY LABELING:

"Identity", as used in this section, is defined as the name and address of the milk plant at which the pasteurization, ultra-pasteurization or aseptic processing takes place. It is recommended that the voluntary national uniform coding system for the identification of pasteurization plants at which milk and milk products are packaged, be adopted in order to provide a uniform system of codes throughout the country.

In cases where several plants are operated by one firm, the common firm name may be utilized on milk bottles or containers. *Provided*, that the location of the plant at which the contents were pasteurized, ultra-pasteurized or aseptically processed is also shown, either directly or by a code. This requirement is necessary in order to enable the regulatory agency to identify the source of the pasteurized, ultra-pasteurized or aseptically processed milk. The street

address of the plant need not be shown when only one plant of a given name is located within the municipality.

The identity labeling requirement may be interpreted as permitting plants and persons to purchase and distribute, under their own label, milk and milk products processed and packaged at another plant, provided, that the label reads, "Processed at ... (name and address)", or that the processing and packaging plant is identified by a proper code.

MISLEADING LABELS: The regulatory agency shall not permit the use of any misleading marks, words or endorsements upon the label. They may permit the use of registered trade designs or similar terms on the bottle cap or label when, in their opinion, they are not misleading and are not so used as to obscure the labeling required by the *Ordinance*. The use of super grade designations shall not be permitted. Grade designations such as "Grade AA Pasteurized", "Selected Grade A Pasteurized", "Special Grade A Pasteurized", "Premium", etc., give the consumer the impression that such a grade is significantly safer than Grade "A". Such an implication is false, because the *Ordinance* requirements for Grade "A" pasteurized, ultra-pasteurized or aseptically processed milk when properly enforced, will insure that this grade of milk will be as safe as milk can practically be made.

SECTION 5. INSPECTION OF DAIRY FARMS AND MILK PLANTS

Each dairy farm, milk plant, receiving station, milk tank truck cleaning facility and transfer station whose milk or milk products are intended for consumption within

...of...⁹ or its jurisdiction, and each bulk milk hauler/sampler who collects samples of raw milk for pasteurization, for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, receiving station or transfer station and his bulk milk pickup tank and its appurtenances shall be inspected by the regulatory agency prior to the issuance of a permit. Following the issuance of a permit, the regulatory agency shall:

1. Inspect each milk tank truck and its appurtenances used by a bulk milk hauler/sampler who collects samples of raw milk for pasteurization for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, receiving station or transfer station, at least once every 12 months;

2. Inspect each such bulk milk hauler/sampler's pickup and sampling procedures at least once every 24 months;

3. Inspect each milk plant and receiving station at least once every 3 months.

4. Inspect each milk tank truck cleaning facility and transfer station at least once every 6 months; and

5. Inspect each dairy farm at least once every 6 months.¹⁰

Should the violation of any requirement set forth in Section 7, or in the case of a bulk milk hauler/sampler also Section 6 and Appendix B, be found to exist on an

⁹ Substitute proper legal jurisdiction here and in all similar places throughout the Ordinance.

¹⁰ Communities and/or States desiring to inspect dairy farms under a performance-based inspection system should substitute the following language in 5. "5. Inspect each dairy farm as provided in Appendix P, Performance-Based Dairy Farm Inspection System."

inspection, a second inspection shall be required after the time deemed necessary to remedy the violation, but not before 3 days. This second inspection shall be used to determine compliance with the requirements of Section 7 or in the case of a bulk milk hauler/sampler or milk tank truck also Section 6 and Appendix B. Any violation of the same requirement of Section 7, or in the case of a bulk milk hauler/sampler or milk tank truck also Section 6 and Appendix B on such second inspection, shall call for permit suspension in accordance with Section 3 and/or court action. *Provided*, that when the regulatory agency finds that a critical processing element violation involving:

1. Proper pasteurization, whereby every particle of milk or milk product may not have been heated to the proper temperature and held for the required time in properly designed and operated equipment; or
2. A cross-connection exists whereby direct contamination of pasteurized milk or milk product is occurring; or
3. Conditions exist whereby direct contamination of pasteurized milk or milk product is occurring.

The regulatory agency shall take immediate action to prevent further movement of such milk or milk product until such violations of critical processing element(s) have been corrected. Should correction of such critical processing element(s) not be accomplished immediately, the regulatory agency shall take prompt action to suspend the permit as provided for in Section 3 of this *Ordinance*. *Provided*, that in the case of dairy plants producing aseptically processed milk and milk products, when an inspection of the dairy plant and its records reveal that the process used has been less than the required scheduled process, it shall be considered an imminent hazard to public health and the

regulatory agency shall take immediate action to suspend the permit of the plant for the sale of aseptically processed milk and milk products in conformance with Section 3 of this *Ordinance*.

One copy of the inspection report shall be handed to the operator, or other responsible person or be posted in a conspicuous place on an inside wall of the establishment. Said inspection report shall not be defaced and shall be made available to the regulatory agency upon request. An identical copy of the inspection report shall be filed with the records of the regulatory agency.

Every milk producer, bulk milk hauler/sampler, milk transportation company or milk tank truck driver, distributor or plant operator shall, upon request of the regulatory agency, permit access of officially designated persons to all parts of their establishment or facilities to determine compliance with the provisions of this *Ordinance*. A distributor or plant operator shall furnish the regulatory agency, upon request, for official use only, a true statement of the actual quantities of milk and milk products of each grade purchased and sold, a list of all sources of such milk and milk products, records of inspections, tests and pasteurization time and temperature records.

It shall be unlawful for any person who, in an official capacity, obtains any information under the provisions of this *Ordinance* which is entitled to protection as a trade secret (including information as to the quantity, quality, source or disposition of milk or milk products, or results of inspections or tests thereof) to use such information to their own advantage or to reveal it to any unauthorized person.

ADMINISTRATIVE PROCEDURES

INSPECTION FREQUENCY: For the purposes of determining the inspection frequency for dairy farms and transfer stations the interval shall include the designated six month period plus the remaining days of the month in which the inspection is due.

For the purposes of determining the inspection frequency for milk plants and receiving stations the interval shall include the designated three month period plus the remaining days of the month in which the inspection is due.

One milk tank truck inspection every 12 months, or bulk milk hauler/sampler pickup and sampling procedures inspection each 24 months, or one producer inspection every 6 months or one plant inspection every 3 months is not a desirable frequency, it is instead a legal minimum. Bulk milk hauler/samplers, milk tank trucks, dairy farms and milk plants experiencing difficulty meeting requirements should be visited more frequently. Inspections of dairy farms shall be made at milking time as often as possible and of milk plants at different times of the day in order to ascertain if the processes of equipment assembly, sanitizing, pasteurization, cleaning and other procedures comply with the requirements of this *Ordinance*.

ENFORCEMENT PROCEDURES: This section provides that a dairy farm, bulk milk hauler/sampler, milk tank truck, milk tank truck driver or milk plant, except those processing aseptically processed milk and milk products, shall be subject to suspension of permit and/or court action, if two successive inspections disclose a violation of the same requirement.

Experience has demonstrated that strict enforcement of the *Ordinance* leads to a better and friendlier relationship between

the regulatory agency and the milk industry than does a policy of enforcement which seeks to excuse violations and to defer penalty thereof. The sanitarian's criterion of satisfactory compliance should be neither too lenient nor unreasonably stringent. When a violation is discovered, the sanitarian should point out to the milk producer, responsible person for the milk tank truck, bulk milk hauler/sampler, milk tank truck driver or plant operator the requirement that has been violated, discuss a method for correction and set a time for correcting the violated requirement.

The penalties of suspension or revocation of permit, and/or court action, are provided to prevent continued violation of the provisions of this *Ordinance*, but are worded to protect the dairy industry against unreasonable or arbitrary action. When a condition is found which constitutes an imminent health hazard, prompt action is necessary to protect the public health; therefore, the regulatory agency is authorized, in Section 3, to suspend the permit immediately. However, except for such emergencies, no penalty is imposed on the producer, responsible person for the milk tank truck, bulk milk hauler/sampler, milk tank truck driver or distributor upon the first violation of any of the sanitation requirements listed in Section 7. A producer, milk transportation company, bulk milk hauler/sampler, milk tank truck driver or distributor found violating any requirement must be notified in writing and given a reasonable time to correct the violation(s) before a second inspection is made, but not before three days. The requirement of giving written notice shall be deemed to have been satisfied by the handing to the operator or by the posting of an inspection report, as required by this section. After receipt of a notice of violation, but before the allotted time has elapsed, the producer, milk transportation company, bulk milk

hauler/sampler, milk tank truck driver or distributor shall have an opportunity to appeal the sanitarian's interpretation to the regulatory agency or for an extension of the time allowed for correction.

ENFORCEMENT PROCEDURES--ASEPTIC PROCESSING MILK PLANTS:

Because aseptically processed milk and milk products are stored at room temperature and are not refrigerated after processing they must be considered an imminent hazard to public health whenever it is revealed by an inspection or a review of the processing records that the process is less than the required scheduled process and the products produced have not maintained their commercial sterility. Prompt action by the regulatory agency to suspend the permit must be initiated in order to protect the public health. The regulatory agency shall stop the sale of all under-processed product and follow at least the minimum requirements of 21 CFR 113.89 (See Appendix L) before releasing any product.

CERTIFIED INDUSTRY INSPECTION:

The regulatory agency may certify industry personnel to carry out cooperatively the provisions of this *Ordinance* with respect to the supervision of dairy farms and haulers pickup and sampling procedures. States utilizing certified industry inspections shall have on file and available for review, a written program that describes how the requirements of the PMO and related documents shall be implemented.

Reports of all inspections conducted by such personnel to determine compliance with the provisions of this *Ordinance* shall be maintained by the industry at a location acceptable to the regulatory agency. All punitive actions and all inspections for the issuance or reinstatement of permits may be performed by the Certified Industry

Inspector. Initial inspections and change of market inspections are required and shall be conducted by the state regulatory agency in conjunction with the Certified Industry Inspector.

When a producer changes market, the producer records for the preceding 24 months shall be transferred with the producer (through the state regulatory agency) and will continue to be a part of the producer's record.

Industry personnel shall be certified every 3 years, by the regulatory agency.

At least annually, the Certified Industry Inspector shall attend an educational seminar provided by the State Regulatory Agency, or equivalent training acceptable to the State Regulatory Agency.

At least once in each 6 month period, the State Regulatory Agency shall inspect the records maintained by the Industry for the Certified Industry Inspection Program and conduct farm field work to assure the program meets the provisions of the State's written plan and requirements of the *Grade "A" Pasteurized Milk Ordinance* and related documents.

Initial certification by the regulatory agency shall not be made during the course of an official inspection. Re-certification by the regulatory agency may be conducted during the course of an official inspection.

Purpose of Certification--The purpose of certification is to have the applicant formally demonstrate their inspection ability to apply proper interpretations of the *Grade "A" Pasteurized Milk Ordinance*, related documents, and the agencies procedures.

Designation of Individuals to Be Certified--Candidates shall submit requests for certification to the regulatory agency. The applicant for certification shall have had experience in the field of milk sanitation, and shall be an employee of a milk plant, a producer association or officially designated laboratory or shall be employed on a consulting basis.

Recording of Qualification Data--Prior to conducting the certification procedure, background information shall be secured on the applicant. This shall include academic training, experience in milk sanitation and related fields, in-service courses attended, etc. This information is to be retained by the regulatory agency as part of the applicant's file, along with appropriate records of the applicant's performance during the certification examination.

Field Procedure--Only one applicant shall be certified at a time. The certification is to be conducted without prompting from the regulatory agency or comparison of inspection results in any way until the entire procedure is completed. Certification shall not be made during the course of an official inspection by the regulatory agency.

At least 25 randomly selected dairy farms shall be visited. After the necessary inspections have been completed, the regulatory agency shall compare their results with those of the candidate. The percentage agreement for each item of sanitation shall be determined by dividing the number of agreements by the total number of dairy farms that were inspected.

Criteria for Certification--In order to be certified, an industry inspector shall agree with the regulatory agency 80 percent of the time on individual items of sanitation and shall further agree to comply with the

administrative procedures established by the regulatory agency for the program of dairy farm supervision. The regulatory agency should allow sufficient time to discuss the inspector's findings with the applicant.

Duration of Certification--Certification of industry inspection personnel shall be for a period not exceeding 3 years from the date of formal certification or re-certification unless revoked.

Re-certification--The regulatory agency shall notify the certified industry inspector of the need for certification renewal at least 60 days prior to its expiration. If re-certification is desired, the inspector will make appropriate arrangements for the renewal procedure. Re-certification can be made for the succeeding 3-year period, by following the procedures outlined above. *Provided*, that re-certification may be conducted during the course of an official inspection by the regulatory agency.

Reports and Records--Upon satisfactory completion of certification or re-certification, the certified industry inspector shall be issued a certificate. The milk plant(s) or officially designated laboratory(ies) employing the inspector shall be formally notified by letter of the certification. The letter shall outline the purpose of the certification and the conditions under which the certification may be retained. A copy of the notification letter, together with a copy of the qualification data above and a resume of the percentage agreement on individual items, shall be retained by the regulatory agency.

Revocation of Certification--The certification of an industry inspector may be revoked by the regulatory agency upon a finding that the inspector is:

1. Not in agreement with the regulatory agency at least 80 percent of the time on items of sanitation in a field examination conducted as described in the *Field Procedure* outlined above; or

2. Not complying with the established administrative procedures of the regulatory agency for the program; or

3. Failing to carry out the provisions of the *Grade "A" Pasteurized Milk Ordinance* in the course of the inspector's work.

INSPECTION REPORTS: A copy of the inspection report shall be filed as directed by the regulatory agency and retained for at least 24 months. The results shall be entered on appropriate ledger forms. The use of a computer or other information retrieval system may be used. Examples of field inspection forms are included in Appendix M.

SECTION 6. THE EXAMINATION OF MILK AND MILK PRODUCTS

It shall be the responsibility of the bulk milk hauler/sampler to collect a representative sample of milk from each farm bulk tank prior to transferring milk from a farm bulk tank, truck or other container. All samples shall be collected and delivered to a milk plant, receiving station, transfer station or other location approved by the regulatory agency.

During any consecutive six months, at least four samples of raw milk for pasteurization shall be collected, in at least four separate months, except when three months show a month containing two sampling dates separated by at least 20 days, and delivered in accordance with this section from each producer. These samples shall be obtained under the direction of the regulatory agency or shall be taken from each

producer under the direction of the regulatory agency.

During any consecutive six months, at least four samples of raw milk for pasteurization, ultra-pasteurization or aseptic processing, collected in at least four separate months, except when three months show a month containing two sampling dates separated by at least 20 days, shall be taken, by the regulatory agency, from each milk plant after receipt of the milk by the plant and prior to pasteurization, ultra-pasteurization or aseptic processing.

During any consecutive six months, at least four samples of heat-treated milk products, from plants offering such products for sale, shall be collected in at least four separate months, except when three months show a month containing two sampling dates separated by at least 20 days, by the regulatory agency.

During any consecutive six months, at least four samples of pasteurized milk, flavored milk, flavored reduced fat or lowfat milk, flavored nonfat (skim) milk, each fat level of reduced fat or lowfat milk and each milk product defined in this *Ordinance*, except aseptically processed shall be collected in at least four separate months, except when three months show a month containing two sampling dates separated by at least 20 days, from every milk plant, by the regulatory agency.

Samples of milk and milk products shall be taken while in the possession of the producer or distributor at any time prior to delivery to the store or consumer. Samples of milk and milk products from dairy retail stores, food service establishments, grocery stores and other places where milk and milk products are sold shall be examined periodically as determined by the regulatory agency and the results of such examination shall be used to determine compliance with Sections 2, 4 and 10. Proprietors of such establishments shall furnish the regulatory

agency, upon request, with the names of all distributors from whom milk or milk products are obtained.

Required bacterial counts, somatic cell counts and cooling temperature checks shall be performed on raw milk for pasteurization. In addition, drug tests on each producer's milk shall be conducted at least four times during any consecutive 6 months. Required bacterial counts, drug tests, coliform determinations, phosphatase and cooling temperature checks shall be performed on pasteurized milk and milk products. Required drug residue tests shall be performed on aseptically processed milk and milk products

Whenever two of the last four consecutive bacterial counts (except those for aseptically processed milk and milk products), somatic cell count, coliform determinations, or cooling temperatures, taken on separate days, exceed the limit of the standard for the milk and/or milk products, the regulatory agency shall send a written notice thereof to the person concerned. This notice shall be in effect so long as two of the last four consecutive samples exceed the limit of the standard. An additional sample shall be taken within 21 days of the sending of such notice, but not before the lapse of 3 days. Immediate suspension of permit, in accordance with Section 3, and/or court action shall be instituted whenever the standard is violated by three of the last five bacterial counts (except those for aseptically processed milk and milk products), coliform determinations, cooling temperatures or somatic cell counts.

Whenever a phosphatase test is positive, the cause shall be determined. Where the cause is improper pasteurization, it shall be corrected and any milk or milk product involved shall not be offered for sale.

Whenever a pesticide residue test is positive, an investigation shall be made to

determine the cause and the cause shall be corrected. An additional sample shall be taken and tested for pesticide residues and no milk or milk products shall be offered for sale until it is shown by a subsequent sample to be free of pesticide residues or below the actionable levels established for such residues.

Whenever a drug residue test is positive, an investigation shall be made to determine the cause, and the cause shall be corrected in accordance with the provisions of Appendix N.

Whenever a container or containers of aseptically processed milk or milk product is found to be unsterile, due to under-processing, the regulatory agency shall consider this to be an imminent hazard to public health and shall suspend the permit of the milk plant for the sale of aseptically processed milk and milk products. No aseptically processed milk and milk product shall be sold until it can be shown that the processes, equipment and procedures used are suitable for consistent production of a sterile product. All product from the lot that was found to contain one or more unsterile units shall be recalled and disposed of as directed by the regulatory agency.

Samples shall be analyzed at an official or appropriate officially designated laboratory. All sampling procedures and required laboratory examinations shall be in substantial compliance with the most current edition of *Standard Methods for the Examination of Dairy Products* of the American Public Health Association, and the most current edition of *Official Methods of Analysis of the Association of Official Analytical Chemists*. Such procedures, including the certification of sample collectors and examinations shall be evaluated in accordance with the *Evaluation of Milk Laboratories, United States Public Health Service/Food and Drug Administration*. Aseptically processed milk and milk pro-

ducts packaged in hermetically sealed containers shall be tested in accordance with the FDA's *Bacteriological Analytical Manual*. Examinations and tests to detect adulterants, including pesticides, shall be conducted as the regulatory agency requires. Assays of milk and milk products to which vitamin(s) A and/or D have been added, shall be made at least annually in a laboratory which has been accredited by the U. S. Food and Drug Administration and which is acceptable to the regulatory agency, using test methods acceptable to FDA and other official methodologies which gives statistically equivalent results to the FDA methods. Vitamin testing laboratories are accredited if they have one or more certified analysts and meet the quality control requirements of the program established by the FDA. Laboratory accreditation and analyst certification parameters are specified in the *Evaluation of Milk Laboratories* manual.

In addition, all facilities fortifying products with vitamins must keep volume control records. These volume control records must cross reference the form and amount of vitamin D, vitamin A and/or vitamin A & D used with the amount of products produced and indicate a percent of expected use, plus or minus.

ADMINISTRATIVE PROCEDURES

ENFORCEMENT PROCEDURES: All violations of bacteria, coliform, confirmed somatic cell counts and cooling temperature standards should be followed promptly by inspection to determine and correct the cause. (See Appendix E, Examples of 3-out-of-5 Compliance Enforcement Procedures).

Aseptically processed milk and milk products packaged in hermetically sealed containers are exempt from the refrigerated storage requirements of this *Ordinance*.

Therefore, whenever a breakdown in the processing or packaging of these products occurs an imminent hazard to public health exists. Prompt action is needed by the regulatory agency. Dairy plants aseptically processing milk and milk products in hermetically sealed containers should be encouraged to perform bacterial and other quality tests on each lot of aseptically processed milk and milk product produced in order to ascertain that these products have been properly processed and have not been rendered non-sterile after aseptic processing and packaging. The regulatory agency may utilize industry records, of each lot of aseptically processed milk and milk products, to determine when lots can be released for sale after a violation of the bacterial standards has existed.

LABORATORY TECHNIQUES:

Procedures for the collection and holding of samples; the selection and preparation of apparatus, media and reagents; and the analytical procedures, incubation, reading and reporting of results, shall be in substantial compliance with *Standard Methods for the Examination of Dairy Products and the Official Methods of Analysis*. The procedures shall be those specified therein for:

1. Standard plate count at 32°C (agar or petrifilm method).
2. Alternate methods, including Plate Loop Count with petrifilm, for viable counts for raw milk, and the petrifilm method, for pasteurized milk and milk products, at 32°C.
3. Coliform test with solid media or petrifilm method at 32°C for all milk and milk products, and Petrifilm High Sensitivity Coliform count method for all milk and milk products except unflavored whole, reduced or low fat and nonfat (skim) milk.

4. Beta lactam methods which have been independently evaluated or evaluated by FDA and have been found acceptable by FDA for detecting drug residues in raw milk, or pasteurized milk, or that particular type of pasteurized milk product at current safe or tolerance levels shall be used for each drug of concern.

Regulatory action shall be taken on all positive results (see Appendix N). A result shall be considered positive if it has been obtained by using a method which has been evaluated and deemed acceptable by FDA at levels established in memoranda transmitted periodically by FDA as required by Section III of Appendix N.

5. Screening and confirmatory methods for the detection of abnormal milk.

6. APHA or AOAC phosphatase tests.

7. Vitamin testing shall be performed using test methods acceptable to the FDA and other official methodologies which give statistically equivalent results to the FDA methods.

8. Any other tests which have been approved by the Food and Drug Administration to be equally accurate, precise and practical.

9. All standards used in the development and use of drug residue detection methods designed for PMO monitoring programs will be referenced to a United States Pharmacopeia (USP) standard when available. When a USP standard is not available, then the original method must define the standard to be used.

10. Procedural or reagent changes for official tests must be submitted to the Food and Drug Administration for acceptance prior to being used by certified NCIMS milk laboratories.

The phosphatase test is an index of the efficiency of the pasteurization process. In the event the laboratory phosphatase test is positive, the cause shall be determined

immediately. Where the cause is improper pasteurization, it shall be corrected. When a laboratory phosphatase test is positive, or if any doubt should arise as to the compliance of the equipment, standards or methods outlined in Section 7., Item 16p., the regulatory agency should immediately conduct field phosphatase test at the plant (See Appendix G).

The Wisconsin Mastitis Test or California Mastitis Test may be used for screening raw goat milk samples, to indicate a range of somatic cell levels, as long as the somatic cell standard for goat milk remains 1,000,000/ml.

Any of the following confirmatory or screening tests shall be used: Direct Microscopic Somatic Cell Counting Single Strip Procedure, Electronic Somatic Cell Counting, Flow Cytometry/Opto-Electronic Somatic Cell Counting or Membrane Filter DNA Somatic Cell Counting. Pyronine Y-Methyl green stain or 'New York modification' shall be used in the confirmatory test for Direct Microscopic Somatic Cell Counts in goat milk.

Laboratories using the Wisconsin Mastitis Test, Modified Whiteside or California Mastitis Test for goat milk shall confirm samples of herd milk which exceeds 18mm, or a value of one (1), respectively.

The results of the screening test or confirmatory test shall be recorded on the official records of the dairy farm and a copy of the results sent to the milk producer.

When a warning letter has been sent, because of excessively high somatic cell counts, an official inspection of the dairy should be made by regulatory personnel or certified industry personnel. This inspection should be made during milking time.

SAMPLING PROCEDURES: The *Standard Methods for the Examination of Dairy Products* contains guidance for sampling of products. See Appendix G for a

reference to drug residues in milk and the conditions under which a positive phosphatase reaction may be encountered in properly pasteurized milk or cream. See Appendix B for reference to farm bulk milk hauling programs regarding training, licensing/permitting, routine inspection and the evaluation of sampling procedures.

SECTION 7. STANDARDS FOR GRADE "A" MILK AND MILK PRODUCTS

All Grade "A" raw milk for pasteurization, ultra-pasteurization or aseptic processing and all Grade "A" pasteurized, ultra-pasteurized or aseptically processed milk and milk products shall be produced, processed and pasteurized, ultra-pasteurized or aseptically processed to conform with the following chemical, bacteriological and temperature standards and the sanitation requirements of this section.

No process or manipulation other than pasteurization, ultra-pasteurization or aseptic processing; processing methods integral therewith; and appropriate refrigeration shall be applied to milk and milk products for the purpose of removing or deactivating microorganisms. *Provided*, that in the bulk shipment of cream, nonfat (skim) milk or reduced fat or lowfat milk, the heating of the raw milk, one time, to temperatures greater than 52°C (125°F) but less than 72°C (161°F), for separation purposes, is permitted when the resulting bulk shipment(s) of cream, nonfat (skim) milk or reduced fat or lowfat milk are labeled heat-treated. In the case of heat-treated cream, the cream may be further heated to less than 75°C (166°F) in a continuing heating process and immediately cooled to 7°C (45°F) or less when necessary for enzyme deactivation (such as lipase reduction) for a functional reason.

Table 1. Chemical, Bacteriological and Temperature Standards		
GRADE "A" RAW MILK AND MILK PRODUCTS FOR PASTEURIZATION, ULTRA-PASTEURIZATION OR ASEPTIC PROCESSING	Temperature.....	Cooled to 7°C (45°F) or less within two hours after milking. <i>Provided</i> , that the blend temperature after the first and subsequent milkings does not exceed 10°C (50°F).
	Bacterial limits.....	Individual producer milk not to exceed 100,000 per ml prior to commingling with other producer milk. Not to exceed 300,000 per ml as commingled milk prior to pasteurization.
	Drugs.....	No positive results on drug residue detection methods as referenced in Section 6 - Laboratory Techniques.
	Somatic Cell Count*.....	Individual producer milk: Not to exceed 750,000 per ml.
GRADE "A" PASTEURIZED MILK AND MILK PRODUCTS AND BULK SHIPPED HEAT - TREATED MILK PRODUCTS	Temperature.....	Cooled to 7°C (45°F) or less and maintained thereat.
	Bacterial limits**.....	20,000 per ml., or gm.***
	Coliform****.....	Not to exceed 10 per ml. <i>Provided</i> , that in the case of bulk milk transport tank shipments, shall not exceed 100 per ml.
	Phosphatase****.....	Less than 350 milliunits/L for fluid products and less than 500 for other milk products by the Fluorometer or Charm ALP or equivalent.
	Drugs**.....	No positive results on drug residue detection methods as referenced in Section 6 - Laboratory Techniques which have been found to be acceptable for use with pasteurized and heat-treated milk and milk products.
GRADE "A" ASEPTICALLY PROCESSED MILK AND MILK PRODUCTS	Temperature.....	None.
	Bacterial limits.....	Refer to 21 CFR 113. 3(e)(1)*****
	Drugs**.....	No positive results on drug residue detection methods as referenced in Section 6 - Laboratory Techniques which have been found to be acceptable for use with aseptically processed milk and milk products.

* Goat Milk 1,000,000

** Not applicable to cultured products.

*** Results of the analysis of dairy products which are weighed in order to be analyzed will be reported in # per gm (See the current edition of the *Standard Methods for the Examination of Dairy Products*).

**** Not applicable to bulk shipped heat-treated milk products.

***** 21 CFR 113.3(e)(1) contains the definition of "COMMERCIAL STERILITY"

STANDARDS FOR GRADE “A” RAW MILK FOR PASTEURIZATION, ULTRA- PASTEURIZATION OR ASEPTIC PROCESSING

ITEM 1r. ABNORMAL MILK

Lactating animals which show evidence of the secretion of abnormal milk in one or more quarters, based upon bacteriological, chemical or physical examination, shall be milked last or with separate equipment and the milk shall be discarded. Lactating animals treated with, or lactating animals which have consumed chemical, medicinal or radioactive agents which are capable of being secreted in the milk and which, in the judgement of the regulatory agency, may be deleterious to human health, shall be milked last or with separate equipment and the milk disposed of as the regulatory agency may direct.

PUBLIC-HEALTH REASON

The health of lactating animal is a very important consideration because a number of diseases of lactating animals, including salmonellosis, staphylococcal infection and streptococcal infection, may be transmitted to man through the medium of milk. The organisms of most of these diseases may get into the milk either directly from the udder or indirectly through infected body discharges which may drop, splash or be blown into the milk.

Bovine mastitis is an inflammatory and, generally, highly communicable disease of the bovine udder. Usually, the inciting organism is a streptococcus of bovine origin (type B), but the disease is often caused by a staphylococcus or other infectious agent. Occasionally lactating animal's udders

become infected with hemolytic streptococci of human origin, which may result in milk-borne epidemics of scarlet fever or septic sore throat. The toxins of staphylococci, and possibly other organisms in milk, may cause severe gastroenteritis. Some of these toxins are not destroyed by pasteurization.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. Milk from lactating animals being treated with medicinal agents, which are capable of being secreted in the milk, is not offered for sale for such a period as is recommended by the attending veterinarian or as indicated on the package label of the medicinal agent.

2. Milk from lactating animals treated with or exposed to insecticides, not approved for use on dairy animals by the U.S. Environmental Protection Agency, is not offered for sale.

3. The regulatory agency requires such additional tests for the detection of abnormal milk as they deem necessary.

4. Bloody, stringy, off-colored milk, or milk that is abnormal to sight or odor, is so handled and disposed of as to preclude the infection of other lactating animals and the contamination of milk utensils.

5. Lactating animal secreting abnormal milk are milked last or in separate equipment which effectively prevents the contamination of the wholesome supply. Abnormal milking equipment is maintained clean to reduce the possibility of re-infecting or cross infection of the dairy animal.

6. Equipment, utensils and containers used for the handling of abnormal milk are not used for the handling of milk to be offered for sale, unless they are first cleaned and effectively sanitized.

7. Processed animal waste derivatives, used as a feed ingredient for any portion of the total ration of the lactating dairy animal, have been:

a. Properly processed in accordance with at least those requirements contained in the Model Regulations for Processed Animal Wastes developed by the Association of American Feed Control Officials; and

b. Do not contain levels of deleterious substances, harmful pathogenic organisms or other toxic substances which are secreted in the milk at any level which may be deleterious to human health.

8. Unprocessed poultry litter and unprocessed recycled animal body discharges are not fed to lactating dairy animals.

ITEM 2r. MILKING BARN, STABLE OR PARLOR--CONSTRUCTION

A milking barn, stable or parlor shall be provided on all dairy farms in which the milking herd shall be housed during milking time operations. The areas used for milking purposes shall:

1. Have floors constructed of concrete or equally impervious materials. *Provided*, convalescent (maternity) pens located in milking areas of stanchion-type barns may be used when they comply with the guidelines specified in Appendix C.III.

2. Have walls and ceilings which are smooth, painted or finished in an approved manner; in good repair; ceiling dust-tight;

3. Have separate stalls or pens for horses, calves and bulls, and not be overcrowded;

4. Be provided with natural and/or artificial light, well distributed, for day and/or night milking;

5. Provide sufficient air space and air circulation to prevent condensation and excessive odors;

PUBLIC-HEALTH REASON

When milking is done elsewhere than in a suitable place provided for this purpose, the milk may be contaminated. Floors constructed of concrete or other impervious materials can be kept clean more easily than floors constructed of wood, earth or similar materials and are; therefore, more apt to be kept clean. Painted, or properly finished walls and ceilings encourage cleanliness. Tight ceilings reduce the likelihood of dust and extraneous material getting into the milk. Adequate light makes it more probable that the barn will be clean and that the lactating animals will be milked in a sanitary manner.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. A milking barn, stable or parlor is provided on all dairy farms.

2. Gutters, floors and feed troughs are constructed of good quality concrete or equally impervious material. Floors shall be easily cleaned (brushed surfaces permitted), be graded to drain, maintained in good repair and free of excessive breaks or worn areas that may create pools.

3. Gravity flow manure channels in milking barns, if used, shall be constructed in accordance with the specifications of Appendix C. II or acceptable to the state regulatory agency.

4. Stall barns, when used with gutter grates over manure storage pits, are designed and constructed in accordance with the specifications of Appendix C IV. or acceptable to the state regulatory agency.

5. Walls and ceilings are finished with wood, tile, smooth-surfaced concrete, cement plaster, brick or other equivalent materials with light colored surfaces. Walls, partitions, doors, shelves, windows and ceilings shall be kept in good repair, and surfaces shall be refinished whenever wear or discoloration is evident.

Whenever feed is stored overhead, ceilings shall be constructed to prevent the sifting of chaff and dust into the milking barn, stable or parlor. If a hay opening is provided from a loft which is open into the milking portion of the barn, such openings shall be provided with a dust-tight door which shall be kept closed during milking operations.

6. Bull pens, maternity and calf stalls and horse stalls are partitioned from the milking portion of the barn. Such portions of the barn that are not separated by tight partitions shall comply with all the requirements of this item.

7. Overcrowding is not evidenced by the presence of calves, lactating animals or other barnyard animals in walks or feed alleys. Inadequate ventilation and excessive odors may also be evidence of an overcrowded barn.

8. The milking barn is provided with natural and/or artificial light to insure that all surfaces and particularly the working areas will be plainly visible. The equivalent of at least 10 foot-candles of light in all working areas shall be provided.

9. Air circulation is sufficient to minimize odors and to prevent condensation upon walls and ceilings.

10. A dust-tight partition, provided with doors that are kept closed except when in actual use, shall separate the milking portion of the barn from any feed room or silo in which feed is ground or mixed, or in which sweet feed is stored.

When conditions warrant, the regulatory agency may approve a barn

without four walls extending from floor to roof, or a shed-type barn provided the requirement of Item 3r., prohibiting animals and fowl from entering the barn is satisfied.

ITEM 3r. MILKING BARN, STABLE OR PARLOR--CLEANLINESS

The interior shall be kept clean. Floors, walls, ceilings, windows, pipelines and equipment shall be free of filth and/or litter and shall be clean. Swine and fowl shall be kept out of the milking area.

Feed shall be stored in a manner that will not increase the dust content of the air or interfere with the cleaning of the floor.

Surcingles, milk stools and antikickers shall be kept clean and stored above the floor.

PUBLIC-HEALTH REASON

A clean interior reduces the chances of contamination of the milk or milk pails during milking. The presence of other animals increases uncleanliness and the potential for the spread of disease.

Clean milk stools and surcingles (or belly straps) reduce the likelihood of contamination of milker's hands between the milking of one lactating animal and the milking of another.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. The interior of the milking barn, stable or parlor is kept clean.

2. Leftover feed in feed mangers appears fresh and is not wet or soggy.

3. The bedding material, if used, does not contain more manure than has accumulated since the previous milking.

4. Outside surfaces of pipeline systems located in the milking barn, stable or parlor are reasonably clean.

5. Gutter cleaners are reasonably clean.

6. All pens, calf stalls and bull pens, if not separated from the milking barn, stable or parlor, are clean.

7. Swine and fowl are kept out of the milking area.

8. Milk stools are not padded and are constructed to be easily cleaned. Milk stools, surcingles and antikickers are kept clean and are stored above the floor in a clean place in the milking barn, stable parlor or milkhouse, when not in use.

9. Gravity flow manure channels in milking barns, if used, shall be maintained in accordance with Appendix C. II.

10. Stall barns, when used with gutter grates over manure storage pits, are operated and maintained in accordance with the specifications of C. IV.

The method of cleaning is immaterial. Dairymen whose barns are provided with water under pressure should scrub the floors after each milking with a stiff-bristled brush. In barns in which water under pressure is not available, the floors may be brushed dry and limed. In the latter event, care should be exercised to prevent caking of the lime. When lime or phosphate is used, it shall be spread evenly on the floor as a thin coating. If clean floors are not maintained by this method, the sanitarian should require cleaning with water.

ITEM 4r. COWYARD

The cowyard shall be graded and drained and shall have no standing pools of water or accumulations of organic wastes. *Provided*, that in loafing or lactating animal-housing areas, lactating animal droppings and soiled bedding shall be removed, or clean bedding added, at sufficiently frequent

intervals to prevent the soiling of the lactating animal's udder and flanks. Waste feed shall not be allowed to accumulate. Manure packs shall be properly drained and shall provide a reasonably firm footing. Swine shall be kept out of the cowyard.

PUBLIC-HEALTH REASON

The cowyard is interpreted to be that enclosed or unenclosed area in which the lactating animals are apt to congregate, approximately adjacent to the barn, including animal-housing areas. This area is; therefore, particularly apt to become filthy with manure droppings, which may result in the soiling of the lactating animal's udders and flanks. The grading and drainage of the cowyard, as far as are practicable, are required because wet conditions are conducive to fly breeding and make it difficult to keep manure removed and the lactating animals clean. If manure and barn sweepings are allowed to accumulate in the cowyard, fly breeding will be promoted, and the lactating animals, because of their habit of lying down, will be more apt to have manure-soiled udders. Lactating animals should not have access to piles of manure, in order to avoid the soiling of udders and the spread of diseases among dairy animals.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. The cowyard, which is the enclosed or unenclosed area adjacent to the milking barn in which the lactating animals may congregate, including animal-housing areas and feed lots, is graded and drained, depressions and soggy areas are filled, and lactating animal's lanes are reasonably dry.

2. Approaches to the barn door and the surroundings of stock watering and feed

stations are solid to the footing of the animals.

3. Wastes from the barn or milkhouse are not allowed to pool in the cowyard. Cowyards which are muddy due to recent rains should not be considered as violating this item.

4. Manure, soiled bedding and waste feed are not stored or permitted to accumulate therein in such a manner as to permit the soiling of cow's udders and flanks. Animal-housing areas (stables without stanchions, such as loose-housing stables, pen stables, resting barns, holding barns, loafing sheds, wandering sheds, free-stall housing) shall be considered as part of the cowyard. Manure packs shall be solid to the footing of the animals (See Appendix C).

5. Cowyards are kept reasonably free of animal droppings. Animal droppings shall not be allowed to accumulate in piles that are accessible to the animals.

ITEM 5r. MILKHOUSE OR ROOM-- CONSTRUCTION AND FACILITIES

A milkhouse or room of sufficient size shall be provided, in which the cooling, handling and storing of milk and the washing, sanitizing and storing of milk containers and utensils shall be conducted. Except as provided for in Item 12r. of this section.

The milkhouse shall be provided with a smooth floor constructed of concrete or equally impervious material, graded to drain and maintained in good repair. Liquid waste shall be disposed of in a sanitary manner. Floor drains shall be accessible and shall be trapped if connected to a sanitary sewer system.

The walls and ceilings shall be constructed of smooth material, be in good repair and be well painted, or finished in an equally suitable manner.

The milkhouse shall have adequate natural and/or artificial light and be well ventilated.

The milkhouse shall be used for no other purpose than milkhouse operations. There shall be no direct opening into any barn, stable or parlor or into a room used for domestic purposes. *Provided*, that a direct opening between the milkhouse and milking barn, stable or parlor is permitted when a tight-fitting, self-closing, solid door (s) hinged to be single or double acting is provided. Screened vents in the wall between the milkhouse and a breezeway, which separates the milkhouse from the milking parlor, are permitted, provided animals are not housed within the milking facility.

Water under pressure shall be piped into the milkhouse.

The milkhouse shall be equipped with a two-compartment wash vat and adequate hot water heating facilities.

A transportation tank may be used for the cooling and/or storage of milk on the dairy farm. Such tank shall be provided with a suitable shelter for the receipt of milk. Such shelter shall be adjacent to, but not a part of, the milkroom and shall comply with the requirements of the milkroom with respect to construction items, lighting, drainage, insect and rodent control and general maintenance. In addition, the following minimum criteria shall be met:

1. An accurate, accessible temperature recording device shall be installed in the milk line downstream from an effective cooling device which cools the milk to 7° C (45° F) or less.
2. The milk shall be sampled at the direction of the regulatory agency in a manner so as to preclude contaminating the tanker or sample, by an acceptable milk sample collector.

3. The milk tank truck shall be effectively agitated in order to collect a representative sample.

When the regulatory agency determines conditions exist whereby the milk tank truck can be adequately protected and sampled without contamination, a shelter need not be provided if the following minimum criteria are met:

1. The milk hose connection is accessible to, and made from within, the milkroom. The milk hose connection to the milk tank truck is completely protected from the outside environment at all times.
2. To assure continued protection of the milk, the milk tank truck manhole must be sealed after the truck has been cleaned and sanitized.
3. The milk tank truck shall be washed and sanitized at the dairy plant receiving the milk or at a wash station acceptable to the regulatory agency.
4. To prevent overflow from the milk tank truck which would create unsanitary conditions around the milk house, the milk tank truck shall be equipped with a liquid level sensor device of sanitary design. The sensor device shall deactivate the milk pump or sound an alarm when activated.
5. An accurate, accessible temperature recording device shall be installed in the milk line downstream from an effective cooling device which cools the milk to below 7°C (45°F).
6. The milk shall be sampled at the direction of the regulatory agency, in a manner so as to preclude contaminating the milk tank truck or sample, by a permitted milk sample collector, or the equivalent. The milk in the milk tank truck shall be

effectively agitated in order to collect a representative sample.

7. The milk tank truck shall be parked on a self-draining concrete or equally impervious surface during filling and storage.

PUBLIC-HEALTH REASON

Unless a suitable, separate place is provided for the cooling, handling and storing of milk and for the washing, sanitizing and storage of milk utensils, the milk or the utensils may become contaminated. Construction which permits easy cleaning promotes cleanliness. A well drained floor of concrete or other impervious material promotes cleanliness. Ample light promotes cleanliness, and proper ventilation reduces the likelihood of odors and condensation. A well equipped milkhouse which is separated from the barn, stable or parlor and the living quarters provides a safeguard against the exposure of milk and milk utensils to infection from persons, other than regular milk handlers, and from insects and dust.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. A separate milkhouse of sufficient size is provided for the cooling, handling and storing of milk and the washing, sanitizing and storing of milk containers and utensils. Except as provided for in Item 12r. of this section.

2. The floors of all milkhouses are constructed of good quality concrete (float finish permissible), or equally impervious tile, or brick laid closely with impervious material, or metal surfacing with impervious joints or other material the equivalent of concrete and maintained free of breaks, depressions and surface peelings.

3. The floor slopes to drain so that there are no pools of standing water. The joints between the floor and the walls shall be watertight.

4. The liquid wastes are disposed of in a sanitary manner. All floor drains are accessible and are trapped if connected to a sanitary sewer.

5. Walls and ceilings are constructed of smooth dressed lumber or similar material; well painted with a light-colored washable paint; and are in good repair. Surfaces and joints shall be tight and smooth. Sheet metal, tile, cement block, brick, concrete, cement plaster or similar materials of light color may be used and the surfaces and joints shall be smooth.

6. A minimum of 20 foot-candles of light is provided at all working areas from natural and/or artificial light for milkhouse operations.

7. The milkhouse is adequately ventilated to minimize condensation on floors, walls, ceilings and clean utensils.

8. Vents, if installed, and lighting fixtures are installed in a manner to preclude the contamination of bulk milk tanks or clean utensil storage areas.

9. The milkhouse is used for no other purpose than milkhouse operations.

10. There is no direct opening into any barn, stable or parlor or room used for domestic purposes. Except that an opening between the milkhouse and milking barn, stable or parlor is permitted when a tight-fitting, self-closing, solid door(s) hinged to be single or double acting is provided. Except that screened vents are permitted in the wall between the milkhouse and a breezeway, which separates the milkhouse from the milking parlor, provided animals are not housed within the milking facility.

11. A vestibule, if used, complies with the applicable milkhouse construction requirements.

12. The transfer of milk from a bulk-holding cooling tank to a transport tank is through a hose port located in the milkhouse wall. The port shall be fitted with a tight door, which shall be in good repair. It shall be kept closed except when the port is in use. An easily cleanable surface shall be constructed under the hose port, adjacent to the outside wall and sufficiently large to protect the milk hose from contamination.

13. Water under pressure is piped into the milkhouse.

14. Each milkhouse is provided with facilities for heating water in sufficient quantity and to such temperatures for the effective cleaning of all equipment and utensils (See Appendix C).

15. The milkhouse is equipped with a wash-and-rinse vat having at least two compartments. Each compartment must be of sufficient size to accommodate the largest utensil or container used. The upright wash vat for milk pipelines and milk machines may be accepted as one part of the two-compartment vat. *Provided*, that the stationary wash rack, in or on the vat, and the milking machines inflations and appurtenances are completely removed from the vat during the washing, rinsing and/or sanitizing of other utensils and equipment. Where mechanical cleaning/recirculated systems eliminate the need for handwashing of equipment, the presence of the second wash vat compartment may be optional, if so determined by the State Regulatory Agency, on an individual farm basis.

16. A transportation tank, with or without overhead protection may be used for cooling and storing milk on a dairy farm. If a suitable shelter is provided for a transportation truck used for cooling and storing milk, such shelter shall be adjacent to, but not a part of, the milkroom and shall comply with the prerequisites of the milkroom with respect to construction items, lighting, drainage, insect and rodent control

and general maintenance. See Appendix C for suggested plans and information on size, construction, operation and maintenance of milkhouses. In addition, the following minimum criteria shall be met:

1. An accurate, accessible temperature recording device shall be installed in the milk line downstream from an effective cooling device which cools the milk to 7°C (45° F) or less.

2. The milk shall be sampled at the direction of the regulatory agency in a manner so as to preclude contaminating the milk tank truck or sample, by an acceptable milk sample collector.

3. The milk tank truck shall be effectively agitated in order to collect a representative sample.

When the regulatory agency determines conditions exist whereby the milk tank truck can be adequately protected and sampled without contamination, a shelter need not be provided if the following minimum criteria are met:

1. The milk hose connection is accessible to, and made from within, the milkroom. The milk hose connection to the milk tank truck is completely protected from the outside environment at all times.

2. To assure continued protection of the milk, the milk tank truck manhole must be sealed after the truck has been cleaned and sanitized.

3. The milk tank truck shall be washed and sanitized at the dairy plant receiving the milk or at a wash station acceptable to the regulatory agency.

4. To prevent overflow from the milk tank truck which would create unsanitary conditions around the milk house, the milk tank truck shall be equipped with a liquid level sensor device of sanitary design. The sensor device shall deactivate the milk pump or sound an alarm when activated.

5. An accurate, accessible temperature recording device shall be

installed in the milk line downstream from an effective cooling device which cools the milk to below 7°C (45° F).

6. The milk shall be sampled at the direction of the regulatory agency, in a manner so as to preclude contaminating the milk tank truck or sample, by a permitted milk sample collector, or the equivalent. The milk in the milk tank truck shall be effectively agitated in order to collect a representative sample.

7. The milk tank truck shall be parked on a self-draining concrete or equally impervious surface during filling and storage.

ITEM 6r. MILKHOUSE OR ROOM-- CLEANLINESS

The floors, walls, ceilings, windows, tables, shelves, cabinets, wash vats, non-product-contact surfaces of milk containers, utensils and equipment and other milkroom equipment shall be clean. Only articles directly related to milkroom activities shall be permitted in the milkroom. The milkroom shall be free of trash, animals and fowl.

PUBLIC-HEALTH REASON

Cleanliness in the milkroom reduces the likelihood of contamination of the milk.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. The milkroom structure, equipment and other milkroom facilities used in its operation or maintenance are clean at all times.

2. Incidental articles such as desks, refrigerators, and storage cabinets may be in the milkroom provided they are kept clean

and ample space is available to conduct the normal operations in the milkroom and will not cause contamination of the milk.

3. Vestibules, if provided, are kept clean.

4. Animals and fowl are kept out of the milkroom.

ITEM 7r. TOILET

Every dairy farm shall be provided with one or more toilets, conveniently located, properly constructed, operated and maintained in a sanitary manner. The waste shall be inaccessible to flies and shall not pollute the soil surface or contaminate any water supply.

PUBLIC-HEALTH REASON

The organisms of typhoid fever, dysentery and gastrointestinal disorders may be present in the body wastes of persons who have these diseases. In the case of typhoid fever, well persons (carriers) also may discharge the organisms in their body wastes. If a toilet is not fly-tight and so constructed as to prevent overflow, infection may be carried from the excreta to the milk, either by flies or through the pollution of ground water supplies or streams to which the lactating animals have access.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. There is at least one flush toilet connected to a public sewer system or to an individual sewage-disposal system or a chemical toilet, earth pit privy or other type of privy. Such sewage systems shall be constructed and operated in accordance with the standards outlined in Appendix C, or when a state or local regulatory agency has more

effective standards designed specifically for that region, these standards may apply, provided, that there is no mixing of animal and human waste..

2. A toilet or privy is convenient to the milking barn and the milkroom. There shall be no evidence of human defecation or urination about the premises.

3. No privy opens directly into the milkroom.

4. The toilet room, including all fixtures and facilities, is kept clean and free of flies and odors.

5. Where flush toilets are used, doors to toilet rooms are tight and self-closing. All outer openings in toilet rooms shall be screened or otherwise protected against the entrance of flies.

6. Vents of earth pits are screened.

ITEM 8r. WATER SUPPLY

Water for milkhouse and milking operations shall be from a supply properly located, protected and operated and shall be easily accessible, adequate and of a safe, sanitary quality.

PUBLIC-HEALTH REASON

A dairy farm water supply should be accessible in order to encourage its use in ample quantity in cleaning operations; it should be adequate so that cleaning and rinsing will be thorough; and it should be of a safe, sanitary quality in order to avoid contamination of milk utensils.

A polluted water supply, used in the rinsing of the dairy utensils and containers, may be more dangerous than a similar water supply which is used for drinking purposes only. Bacteria grow much faster in milk than in water and the severity of an attack of a given disease depends largely upon the size of the dose of disease organisms taken into the system. Therefore, a small number

of disease organisms consumed in a glass of water from a polluted well may possibly result in no harm; whereas, if left in a milk utensil, which has been rinsed with the water, they may after several hours growth, in the milk, increase in such numbers as to cause disease when consumed.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. The water supply for milkhouse and milking operations is approved as safe by the State water control authority and, in the case of individual water systems, complies with the specifications outlined in Appendix D, and the bacteriological standards outlined in Appendix G.

2. No cross-connection exists between a safe water supply and any unsafe or questionable water supply or any other source of pollution.

3. There are no submerged inlets through which a safe water supply may be contaminated.

4. The well or other source of water is located and constructed in such a manner that neither under-ground nor surface contamination from any sewerage systems, privy or other source of pollution can reach such water supply.

5. New individual water supplies and water supply systems which have been repaired or otherwise become contaminated are thoroughly disinfected before being placed in use (See Appendix D). The supply shall be made free of the disinfectant by pumping to waste before any sample for bacteriological testing shall be collected.

6. All containers and tanks used in the transportation of water are sealed and protected from possible contamination. These containers and tanks shall be subjected to a thorough cleaning and a bac-

teriological treatment prior to filling with potable water to be used at the dairy farm. To minimize the possibility of contamination of the water during its transfer from the potable tanks to the elevated or ground-water storage at the dairy farm, a suitable pump, hose and fittings shall be provided. When the pump, hose and fittings are not being used, the outlets shall be capped and stored in a suitable dust-proof enclosure so as to prevent their contamination. The storage tank at the dairy farm shall be constructed of impervious material, provided with a dust and rainproof cover and also provided with an approved-type vent and roof hatch. All new reservoirs or reservoirs which have been cleaned shall be disinfected prior to placing them into service (See Appendix D).

7. Samples for bacteriological examination are taken upon the initial approval of the physical structure, based upon the requirements of this *Ordinance*, when any repair or alteration of the water supply system has been made and at least every 3 years. *Provided*, that water supplies with buried well casing seals, installed prior to the adoption of this section, shall be tested at intervals no greater than 6 months apart. Whenever such samples indicate either the presence of bacteria of the coli-form group or whenever the well casing, pump or seal need replacing or repair, the well casing and seal shall be brought above the ground surface and shall comply with all other applicable construction criteria of this section. *Provided*, that when water is hauled to the dairy farm, such water shall be sampled for bacteriological examination at the point of use and submitted to a laboratory at least four times in separate months during any consecutive six months. Bacteriological examinations shall be conducted in a laboratory acceptable to the regulatory agency. To determine if water samples have been taken at the frequency

established in this section, the interval shall include the designated period plus the remaining days of the month in which the sample is due.

8. Current records of water test results shall be retained on file with the regulatory agency or as the regulatory agency directs.

ITEM 9r. UTENSILS AND EQUIPMENT--CONSTRUCTION

All multi-use containers, equipment and utensils used in the handling, storage or transportation of milk shall be made of smooth, nonabsorbent, corrosion-resistant, nontoxic materials, and shall be so constructed as to be easily cleaned. All containers, utensils and equipment shall be in good repair. Multiple-use woven material shall not be used for straining milk. All single-service articles shall have been manufactured, packaged, transported and handled in a sanitary manner and shall comply with the applicable requirements of Item 11p of this section. Articles intended for single-service use shall not be reused.

Farm holding/cooling tanks, welded sanitary piping and transportation tanks shall comply with the applicable requirements of Items 10p and 11p of this section.

PUBLIC-HEALTH REASON

Milk containers and other utensils without flush joints and seams, without smooth, easily cleaned, and accessible surfaces, and not made of durable, non-corrodible material, are apt to harbor accumulations in which undesirable bacterial growth is supported. Single-service articles which have not been manufactured and handled in a sanitary manner may contaminate the milk.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. All multi-use containers, equipment and utensils, which are exposed to milk or milk products, or from which liquids may drip, drain or be drawn into milk or milk products, are made of smooth impervious, nonabsorbent, safe materials of the following types:

a. Stainless steel of the AISI (American Iron and Steel Institute) 300 series; or

b. Equally corrosion-resistant, nontoxic metal; or

c. Heat-resistant glass; or

d. Plastic or rubber and rubber-like materials which are relatively inert, resistant to scratching, scoring, decomposition, crazing, chipping and distortion, under normal use conditions; are nontoxic, fat resistant, relatively nonabsorbent, relatively insoluble, do not release component chemicals or impart flavor or odor to the product; and which maintain their original properties under repeated use conditions.

2. Single-service articles have been manufactured, packaged, transported and handled in a sanitary manner and comply with the applicable requirements of Item 11p.

3. Articles intended for single-service use are not reused.

4. All containers, equipment and utensils are free of breaks and corrosion.

5. All joints in such containers, equipment and utensils are smooth and free from pits, cracks or inclusions.

6. Mechanically cleaned milk pipelines and return-solution lines are self-draining. If gaskets are used, they shall be self-positioning and of material meeting specifications described in 1. d. above, and

shall be of such design, finish and application as to form a smooth, flush, interior surface. If gaskets are not used, all fittings shall have self-positioning faces designed to form a smooth, flush, interior surface. All interior surfaces of welded joints in pipelines shall be smooth and free of pits, cracks and inclusions.

7. Detailed plans for mechanically cleaned pipeline systems are submitted to the regulatory agency for written approval prior to installation. No alteration or addition shall be made to any milk pipeline system without prior written approval of the regulatory agency.

8. Strainers, if used, are of perforated metal design, or so constructed as to utilize single-service strainer media.

9. All milking machines, including heads, milk claws, milk tubing and other milk-contact surfaces can be easily cleaned and inspected. Pipelines, milking equipment and appurtenances which require a screw driver or special tool shall be considered easily accessible for inspection, providing the necessary tools are available at the milkhouse.

10. Milk cans have umbrella-type lids.

11. Farm holding/cooling tanks, welded sanitary piping and transportation tanks comply with the applicable requirements of Items 10p and 11p of this section.

12. During filling, flexible plastic/rubber hoses may be used between the fill valves of bottom fill bulk milk storage tanks, when needed for functional purposes. Such hoses shall be drainable, be as short as practical, have sanitary fittings, and be supported to maintain uniform slope and alignment. The end fittings of such hoses shall be permanently attached in such a manner that will assure a crevice-free joint between the hose and the fitting, which can be cleaned by mechanical means. The hoses

shall be included as part of a mechanical cleaning system.

NOTE: 3-A Standards: 3-A Sanitary Standards for dairy equipment are promulgated jointly by the Sanitary Standards Subcommittee of the Dairy Industry Committee, the Committee on Sanitary Procedure of the International Association for Food Protection and the Milk Safety Branch, Food and Drug Administration, Public Health Service, Center for Food Safety and Applied Nutrition, Department of Health and Human Services. Equipment manufactured in conformity with 3-A Sanitary Standards complies with the sanitary design and construction standards of the *Ordinance*.

ITEM 10r. UTENSILS AND EQUIPMENT--CLEANING

The product-contact surfaces of all multi-use containers, equipment and utensils used in the handling, storage or transportation of milk shall be cleaned after each usage.

PUBLIC-HEALTH REASON

Milk cannot be kept clean or free of contamination if permitted to come into contact with unclean containers, utensils or equipment.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. There shall be a separate wash manifold for all mechanically cleaned milk pipelines in all new or extensively remodeled facilities.

2. The product-contact surface of all multi-use containers, equipment and utensils

used in the handling, storage or transportation of milk are cleaned after each milking or once every 24 hours for continuous operations.

3. There shall be no partial removal of milk from milk storage/holding tanks by the bulk milk hauler/sampler, except partial pickups may be permitted when the milk storage/holding tank is equipped with a seven-day recording device complying with the specifications of Appendix H or other recording device acceptable to the state regulatory agency provided the milk storage/holding tank shall be clean and sanitized when empty and shall be emptied at least every 72 hours. In the absence of a temperature recording device, partial pickups may be permitted as long as the milk storage/holding tank is completely empty, clean and sanitized prior to the next milking. In the event of an emergency situation, such as in inclement weather, natural disaster, et cetera, a variance may be permitted at the discretion of the state regulatory agency.

ITEM 11r. UTENSILS AND EQUIPMENT--SANITIZATION

The product-contact surfaces of all multi-use containers, equipment and utensils used in the handling, storage or transportation of milk shall be sanitized before each usage.

PUBLIC-HEALTH REASON

Mere cleaning of containers, equipment and utensils does not insure the removal or destruction of all disease organisms which may have been present. Even very small numbers remaining may grow to dangerous proportions, since many kinds of disease bacteria grow rapidly in milk. For this reason, all milk containers,

equipment and utensils must be treated with an effective sanitizer before each usage.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

All product-contact surfaces of multi-use containers, utensils and equipment used in the handling, storage or transportation of milk are sanitized before each usage by one of the following methods, or by any method which has been demonstrated to be equally effective:

1. Complete immersion in hot water at a temperature of at least 77°C (170°F) for at least 5 minutes; or exposure to a flow of hot water at a temperature of at least 77°C (170°F), as determined by the use of a suitable accurate thermometer (at the outlet), for at least 5 minutes.

2. Certain chemical compounds are effective for the sanitization of milk utensils, containers, and equipment. These are contained in 21 CFR 178.1010. and shall be used in accordance with label directions. (See Appendix F, for further discussion of approved sanitizing procedures).

ITEM 12r. UTENSILS AND EQUIPMENT--STORAGE

All containers, utensils and equipment used in the handling, storage or transportation of milk, unless stored in sanitizing solutions, shall be stored to assure complete drainage and shall be protected from contamination prior to use. *Provided*, that pipeline milking equipment such as milker claws, inflations, weigh jars, meters, milk hoses, milk receivers, tubular coolers, plate coolers and milk pumps which are designed for mechanical cleaning and other equipment, as accepted by FDA which

meets these criteria, may be stored in the milking barn or parlor, provided this equipment is designed, installed and operated to protect the product and solution-contact surfaces from contamination at all times.

PUBLIC-HEALTH REASON

Careless storage of milk utensils which previously have been properly treated is apt to result in recontamination of such utensils, thus rendering them unsafe.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. All milk containers, utensils and equipment, including milking machine vacuum hoses, are stored in the milkhouse in a sanitizing solution, or on racks, until used. Pipeline milking equipment such as milker claws, inflations, weight jars, milk hoses, milk receivers, tubular coolers, plate coolers and milk pumps which are designed for mechanical cleaning and other equipment, as accepted by FDA which meets these criteria, may be mechanically cleaned, sanitized and stored in the milking barn or parlor, provided this equipment is designed, installed and operated to protect the product- and solution-contact surface from contamination at all times. Some of the parameters to be considered in determining protection are: proper location of equipment; proper drainage of equipment; and adequate and properly located lighting and ventilation. The milking barn or parlor must be used only for milking. Concentrates may be fed in the barn during milking but the barn shall not be used for the housing of animals. When manual cleaning of product-contact surfaces is necessary, the cleaning shall be done in the milkhouse.

2. Means are provided to effect complete drainage of equipment when such equipment cannot be stored to drain freely.

3. Clean cans or other containers are stored in the milkhouse within a reasonable time after delivery to the dairy farm.

4. Strainer pads, parchment papers, gaskets and similar single-service articles are stored in a suitable container or cabinet and protected against contamination and in a location convenient to their use.

ITEM 13r. MILKING--FLANKS, UDDERS AND TEATS

Milking shall be done in the milking barn, stable or parlor. The flanks, udders, bellies and tails of all milking lactating animals shall be free from visible dirt. All brushing shall be completed prior to milking. The udders and teats of all milking lactating animals shall be clean and dry before milking. Teats shall be treated with a sanitizing solution just prior to the time of milking and shall be dry before milking. Wet hand milking is prohibited.

PUBLIC-HEALTH REASON

If milking is done elsewhere other than in a suitable place provided for this purpose, the milk may become contaminated. Cleanliness of the lactating animals is one of the most important factors affecting the bacterial count of the milk. Under usual farm conditions, lactating animals contaminate their udders by standing in polluted water or by lying down in the pasture or cowyard. Unless the udders and teats are clean and dry before milking, particles of filth or contaminated water are apt to drop or be drawn into the milk. Such contamination of the milk is particularly dangerous because manure may contain the organisms of brucellosis and tuberculosis, and polluted water may contain

the organisms of typhoid fever and other intestinal diseases. Application of sanitizing solutions to the teats followed by thorough drying just prior to the time of milking has the advantage of giving an additional margin of safety with reference to such disease organisms as are not removed by ordinary cleaning and it is helpful in the control of mastitis.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. Milking is done in a milking barn, stable or parlor.
2. Brushing is completed prior to milking.
3. Flanks, bellies, tails and udders are clipped as often as necessary to facilitate cleaning of these areas and are free from dirt. The hair on the udders shall be of such length that it is not incorporated with the teat in the inflation during milking.
4. Udders and teats of all milking animals are clean and dry before milking. Teats shall be cleaned, treated with a sanitizing solution and dry just prior to milking, except that additional alternative udder preparation methods may also be used once they have been evaluated by FDA and found acceptable.
5. Wet hand milking is prohibited.

ITEM 14r. PROTECTION FROM CONTAMINATION

Milking and milkhouse operations, equipment and facilities shall be located and conducted to prevent any contamination of milk, equipment, containers and utensils. No milk shall be strained, poured, transferred or stored unless it is properly protected from contamination.

After sanitization, all containers, utensils and equipment shall be handled in such a manner as to prevent contamination of any product-contact surface.

Vehicles used to transport milk from the dairy farm to the milk plant receiving station or transfer station shall be constructed and operated to protect their contents from sun, freezing and contamination. Such vehicles shall be kept clean, inside and out, and no substance capable of contaminating the milk shall be transported with the milk.

PUBLIC-HEALTH REASON

Because of the nature of milk and its susceptibility to contamination by disease producing bacteria and other contaminants, every effort should be made to provide adequate protection for the milk at all times. This should include the proper placement of equipment so that work areas in the milking barn and milkhouse are not overcrowded. The quality of any air which is used for the agitation or movement of milk or is directed at a milk product-contact surface should be such that it will not contaminate the milk.

The effect of sanitization of equipment can be nullified if the equipment is not protected after sanitizing.

To protect milk during transportation, delivery vehicles must be properly constructed and operated.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. Equipment and operations are so located within the milking barn and milkhouse as to prevent overcrowding and contamination of cleaned and sanitized containers, equipment and utensils by splash, condensation or manual contact.

2. During processing, pipelines and equipment, used to contain or conduct milk and milk products, shall be effectively separated from tanks or circuits containing cleaning and/or sanitizing solutions.

3. All milk which has overflowed, leaked, been spilled or improperly handled is discarded.

4. All product-contact surfaces of containers, equipment and utensils are covered or otherwise protected to prevent the access of insects, dust, condensation and other contamination. All openings, including valves and piping attached to milk storage and milk tank trucks, pumps or vats, shall be capped or otherwise properly protected. Gravity type strainers used in the milkhouse do not have to be covered. Milk pipelines used to convey milk from pre-coolers to the farm bulk tank must be fitted with effective drip deflectors.

5. The receiving receptacle is raised above the floor (as on a dolly or cart), or placed at a distance from the lactating animals, to protect it against manure and splash when milk is poured and/or strained in the milking. Such receptacle shall have a tight-fitting cover, which shall be closed except when milk is being poured.

6. Each pail or container of milk is transferred immediately from the milking barn, stable or parlor to the milkhouse.

7. Pails, cans and other equipment containing milk are properly covered during transfer and storage.

8. Whenever air under pressure is used for the agitation or movement of milk, or is directed at a milk-contact surface, it is free of oil, dust, rust, excessive moisture, extraneous materials and odor, and shall otherwise comply with the applicable standards of Appendix H.

9. Sanitized product-contact surfaces, including farm cooling holding tank openings and outlets, are protected against contact with unsanitized equipment and

utensils, hands, clothing, splash, condensation and other sources of contamination.

10. Any sanitized product-contact surface, which has been otherwise exposed to contamination, is again cleaned and sanitized before being used.

11. Vehicles used to transport milk from the dairy farm to the milk plant, receiving station or transfer station are constructed and operated to protect their contents from sun, freezing and contamination.

12. Vehicles have bodies with solid enclosures and tight, solid doors.

13. Vehicles are kept clean, inside and out.

14. No substance capable of contaminating milk is transported with the milk.

Note: See items 10p and 11p for information on the construction of milk tank trucks.

ITEM 15r. DRUG AND CHEMICAL CONTROL

Cleaners and sanitizers shall be stored in properly identified, dedicated end use containers.

Animal drugs and medications and animal drug and medication administration equipment shall be stored in such a way that milk, milking equipment, wash vats and hand sinks are not subject to contamination.

Animal drugs and medications shall be properly labeled and segregated (lactating from non-lactating).

Unapproved drugs shall not be used.

PUBLIC-HEALTH REASON

Accidental misuse of cleaners or sanitizers can result in adulteration of the milk.

Animal drug or medications can result in adverse reactions in people sensitive to those residues and can contribute to the development of strains of drug resistant human pathogens.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. Cleaners and sanitizers, used on dairy farms, shall be purchased in containers from the manufacturer or distributor which properly identify the contents or, if bulk cleaners and sanitizers are transferred from the manufacturer's or distributor's container, that the transfer only occur into a dedicated end-use container which is specifically designed and maintained according to the manufacturer's specifications for that specific product. The label on the dedicated end-use container shall include the product name, chemical description, use directions, precautionary and warning statement, first aid instructions, container storage and maintenance instructions and the name and address of the manufacturer or distributor.

2. Equipment used to administer medicinals/drugs is not cleaned in the wash vats and is stored so as not to contaminate the milk or milk contact surfaces of equipment.

3. Medicinals/drugs intended for treatment of non-lactating dairy animals are segregated from those medicinals/ drugs used for lactating animals. (Separate shelves in cabinets, refrigerators or other storage facilities satisfies this item).

4. Drugs and medicinals shall be properly labeled to include the name and address of the manufacturer or distributor

(for OTC medicinals/drugs), or veterinary practitioner dispensing the product (for Rx and extra label use medicinals/drugs).

5. Drugs and medicinal labels shall also include:

- a. Directions for use, and prescribed withholding times;
- b. Cautionary statements, if needed; and
- c. Active ingredient(s) in the drug product.

6. Unapproved and/or improperly labeled medicinals/drugs are not used to treat dairy animals and are not stored in the milkhouse, milking barn, stable or parlor.

7. Drugs and medicinals are stored in such a manner that they cannot contaminate the milk or milk product-contact surface of the equipment, containers or utensils.

NOTE: Topical antiseptics, wound dressings (unless intended for direct injection into the teat), vaccines and other biologics, and dosage form vitamins and/or mineral products are exempt from labeling and storage requirements except when it is determined that they are stored in such a manner that they may contaminate the milk or milk product surfaces of containers or utensils.

ITEM 16r. PERSONNEL--HAND-WASHING FACILITIES

Adequate hand-washing facilities shall be provided, including a lavatory fixture with hot and cold, or warm running water, soap or detergent and individual sanitary towels, convenient to the milkhouse, milking barn, stable, parlor and flush toilet.

PUBLIC-HEALTH REASON

The hands of the milker in his preparation for milking come into contact with almost identically the same kind of material as may have contaminated the udders. During the course of their duties and natural habits outside of the milking barn, the milker's hands must be assumed to have been exposed to body discharges. Washing facilities are required in order to increase the assurance that milker's hands will be washed.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. Hand-washing facilities are located convenient to the milkhouse, milking barn, stable, parlor and flush toilet.

2. Hand-washing facilities include soap or detergent, hot and cold, or warm running water, individual sanitary towels and a lavatory fixture. Utensil wash and rinse vats shall not be considered as hand-washing facilities.

ITEM 17r. PERSONNEL-- CLEANLINESS

Hands shall be washed clean and dried with an individual sanitary towel immediately before milking, before performing any milkhouse function and immediately after the interruption of any of these activities. Milkers and bulk milk hauler/samplers shall wear clean outer garments while milking or handling milk, milk containers, utensils, or equipment.

PUBLIC-HEALTH REASON

The reasons for clean hands of the persons doing the milking are similar to those for the cleanliness of the lactating animal's udder. The milker's hands must be

assumed to have been exposed to contamination during the course of his normal duties on the farm and at milking time. Because the hands of all workers frequently come into contact with their clothing it is important that the clothes worn, during milking and the handling of milk, be clean.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. Hands are washed, clean and dried with an individual sanitary towel immediately before milking; before performing any milkhouse function; and immediately after the interruption of any of these activities.

2. Milkers and bulk milk hauler/samplers wear clean outer garments while milking or handling milk, milk containers, utensils; or equipment.

ITEM 18r. RAW MILK COOLING

Raw milk for pasteurization shall be cooled to 10°C (50°F) or less within 4 hours or less of the commencement of the first milking and to 7°C (45°F) or less within 2 hours after the completion of milking. *Provided*, that the blend temperature after the first milking and subsequent milkings does not exceed 10°C (50°F).

PUBLIC-HEALTH REASON

Milk produced by disease-free lactating animals and under clean conditions usually contains relatively few bacteria immediately after milking. These can multiply to enormous numbers in a few hours unless the milk is cooled. However when the milk is cooled quickly to 7°C

(45°F) or less, there is only a slow increase in the numbers of bacteria.

Usually, the bacteria in milk are harmless, and if this were always true there would be no reason to cool milk, except to delay souring. There is; however, no way for the dairyman or regulating officer to be absolutely sure that no disease bacteria have entered the milk, even though observance of the other items of this *Ordinance* will greatly reduce this likelihood. The likelihood of transmitting disease is much increased when the milk contains large numbers of disease bacteria. Therefore, it is extremely important for milk to be cooled quickly, so that small numbers of bacteria, which may have entered, will not multiply.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. Raw milk for pasteurization shall be cooled to 10°C (50°F) or less within 4 hours or less of the commencement of the first milking and to 7°C (45°F) or less within 2 hours after the completion of milking. *Provided*, that the blend temperature after the first milking and subsequent milkings does not exceed 10°C (50°F).

2. Recirculated cold water which is used in plate or tubular coolers or heat exchangers is from a safe source and protected from contamination. Such water shall be tested semiannually and shall comply with the bacteriological standards of Appendix G.

3. All farm bulk milk tanks manufactured after January 1, 2000 shall be equipped with an approved temperature recording device.

- a. The recording device shall be operated continuously and be maintained in a properly

functioning manner. Circular charts shall not overlap.

- b. The recording device shall be verified in a manner acceptable to the regulatory agency by a traceable standard thermometer.
- c. Recording thermometer charts shall be maintained on the premises for a period of a minimum of six (6) months and available to the regulatory agency.
- d. The recording thermometer should be installed in an area convenient to the milk storage tank and acceptable to the regulatory agency.
- e. The recording thermometer sensor shall be located to permit the registering of the temperature of the contents when the tank contains no more than ten percent (10%) of its calibrated capacity.
- f. The recording thermometer shall comply with the current technical specifications for tank recording thermometers.
- g. A recording thermometer and/or any other device that meets the intent of these administrative procedures and technical specifications and is acceptable to the regulatory agency can be used to monitor/record the bulk tank temperature.
- h. The recording thermometer charts shall properly identify the producer, date, and signature of the person removing the chart.

The information from recording thermometer charts on farm bulk milk tanks shall not be used for enforcement purposes except in cases where an imminent health hazard exists or be

debited on state ratings or FDA check ratings until 12-01-01.

In addition, during the interim period, information should be forwarded by states, FDA and the industry to a NCIMS Committee approved by the Executive Board for recommendation to the next NCIMS Conference of appropriate procedures to be taken in areas of enforcement, debits and responsibilities of administration surrounding the use of recording thermometers on farm bulk milk tanks.

ITEM 19r. INSECT AND RODENT CONTROL

Effective measures shall be taken to prevent the contamination of milk, containers, equipment and utensils by insects and rodents and by chemicals used to control such vermin. Milk rooms shall be free of insects and rodents. Surroundings shall be kept neat, clean and free of conditions which might harbor or be conducive to the breeding of insects and rodents. Feed shall be stored in such a manner that it will not attract birds, rodents or insects.

PUBLIC HEALTH REASON

Proper manure disposal reduces the breeding of flies, which are considered capable of transmitting infection by physical contact or through excreta to milk or milk utensils. Flies visit insanitary places, they may carry disease organisms on their bodies and they may carry living bacteria for as long as 4 weeks within their bodies, and they may pass them on to succeeding generations by infecting their eggs. Effective screening tends to prevent the presence of flies, which are a public health menace. Flies may contaminate the milk

with disease germs, which may multiply and become sufficiently numerous to present a public health hazard. The surroundings of a dairy should be kept neat and clean to encourage cleanliness and reduce insect and rodent harborages.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. Surroundings are kept neat, clean and free of conditions which might harbor or be conducive to the breeding of insects and rodents. During fly season, manure shall be spread directly on the fields; or stored for not more than 4 days in a pile on the ground surface and then spread on the fields; or stored for not more than 7 days in an impervious-floored bin, or on an impervious-curbed platform and then spread; or stored in a tight-screened and trapped manure shed; or effectively treated with larvicides; or disposed of in any other manner which controls insect breeding.

2. Manure packs in loafing areas, stables without stanchions, pen stables, resting barns, wandering sheds and free-stall housing are properly bedded and managed to prevent fly breeding.

3. Milkrooms are free of insects and rodents.

4. Milkrooms are effectively screened or otherwise protected against the entrance of vermin.

5. Outer milkhouse doors are tight and self-closing. Screen doors shall open outward.

6. Effective measures are taken to prevent the contamination of milk, containers, utensils and equipment by insects and rodents and by chemicals used to control such vermin. Insecticides and rodenticides, not approved for use in the

milkhouse, shall not be stored in the milkhouse.

7. Only insecticides and rodenticides approved for use by the regulatory agency and/or registered with the U.S. Environmental Protection Agency, are used for insect and rodent control. (See Appendix C, for further information about insect and rodent control.)

8. Insecticides and rodenticides are used only in accordance with manufacturer's label directions and are used so as to prevent the contamination of milk, milk containers, equipment, utensils, feed and water.

9. Have covered boxes, bins or separate storage facilities for ground, chopped or concentrated feed.

10. Feed may be stored in the milking portion of the barn only in such a manner as will not attract birds, flies or rodents. Open feed dollies or carts may be used for distributing the feed, but not storing feed, in the milking barn. Feed dollies, carts, fully automated feeding systems, or other feed containers may be exempt from the use of covers provided, they do not attract birds, insects, or rodents.

NOTE:: A convenient inspection form for producer dairy farms, which summarizes the applicable sanitation requirements is found in Appendix M.

STANDARDS FOR GRADE “A” PASTEURIZED, ULTRA- PASTEURIZED AND ASEPTICALLY PROCESSED MILK AND MILK PRODUCTS

A receiving station shall comply with Items 1p to 15p, inclusive, and 17p, 20p and 22p, except that the partitioning requirement of Item 5p shall not apply.

A transfer station shall comply with Items 1p, 4p, 6p, 7p, 8p, 9p, 10p, 11p, 12p, 14p, 15p, 20p and 22p and as climatic and operating conditions require, the applicable provisions of Items 2p and 3p. *Provided*, that in every case, overhead protection shall be provided.

Facilities for the cleaning and sanitizing of milk tank trucks shall comply with Items 1p, 4p, 6p, 7p, 8p, 9p, 10p, 11p, 12p, 14p, 15p, 20p and 22p and as climatic and operating conditions require, the applicable provisions of Items 2p and 3p. *Provided*, that in every case, overhead protection shall be provided.

ITEM 1p. FLOORS--CONSTRUCTION

The floors of all rooms in which milk or milk products are processed, handled or stored, or in which milk containers, equipment and utensils are washed, shall be constructed of concrete or other equally impervious and easily cleanable material; and shall be smooth, properly sloped, provided with trapped drains and kept in good repair. *Provided*, that cold-storage rooms used for storing milk and milk products need not be provided with floor drains when the floors are sloped to drain to one or more exits. *Provided further*, that storage rooms for storing dry ingredients and/or packaging materials need

not be provided with drains and the floors may be constructed of tightly joined wood.

PUBLIC-HEALTH REASON

Floors constructed of concrete or other similarly impervious material can be kept clean more easily than floors constructed of wood or other pervious or easily disintegrating material. They will not absorb organic matter and are; therefore, more apt to be kept clean and free of odors. Properly sloped floors facilitate flushing and help to avoid undesirable conditions. Trapping of drains prevents sewer gas from entering the plant.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. The floors of all rooms in which milk is handled, processed, or stored or in which milk containers or utensils are washed, are constructed of good quality concrete, or equally impervious tile or brick laid closely with impervious joint material, or metal surfacing with impervious joints, or other material which is the equivalent of good quality concrete. The floors of storage rooms for dry ingredients and/or packaging material may be constructed of tightly joined wood.

2. The floor surface is smooth and sloped, so that there are no pools of standing water after flushing, and the joints between the floor and the walls are impervious.

3. The floors are provided with trapped drains. Cold-storage rooms used for storing milk and milk products need not be provided with floor drains when the floors are sloped to drain to one or more exits. Storage rooms for dry ingredients and/or packaging materials need not be provided with drains.

ITEM 2p. WALLS AND CEILINGS-- CONSTRUCTION

Walls and ceilings of rooms in which milk or milk products are handled, processed or stored, or in which milk containers, utensils and equipment are washed, shall have a smooth, washable, light-colored surface and be in good repair.

PUBLIC-HEALTH REASON

Painted or otherwise properly finished walls and ceilings are more easily kept clean and are; therefore, more apt to be kept clean. A light-colored paint or finish aids in the even distribution of light and the detection of unclean conditions.

ADMINISTRATIVE PROCEDURES

This item is deemed satisfied when:

1. Walls and ceilings are finished with smooth, washable, light-colored impervious materials.

2. Walls, partitions, windows and ceilings are kept in good repair.

ITEM 3p. DOORS AND WINDOWS

Effective means shall be provided to prevent the access of flies and rodents. All openings to the outside shall have solid doors or glazed windows which shall be closed during dusty weather.

PUBLIC-HEALTH REASON

Freedom from flies in the milk plant reduces the likelihood of contamination of the milk. For information on disease transmission by flies see Item 7r, Public-Health Reason.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. All openings to the outer air are effectively protected by:
 - a. Screening; or
 - b. Effective electric screen panels; or
 - c. Fans or air curtains which provide sufficient air velocity so as to prevent the entrance of flies; or
 - d. Properly constructed flaps where it is impractical to use self-closing doors or air curtains; or
 - e. Any effective combination of a, b, c, or d or by any other method which prevents the entrance of flies.
2. All outer doors are tight and self-closing. Screen doors shall open outward.
3. All outer openings are rodent-proofed to the extent necessary to prevent the entry of rodents.

NOTE: The evidence of insects and/or rodents in the plant shall be considered under Item 9p.

ITEM 4p. LIGHTING AND VENTILATION

All rooms in which milk or milk products are handled, processed or stored and/or in which milk containers, equipment and utensils are washed shall be well lighted and well ventilated.

PUBLIC-HEALTH REASON

Ample light promotes cleanliness. Proper ventilation reduces odors and prevents condensation upon interior surfaces.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. Adequate light sources are provided (natural, artificial or a combination of both) which furnish at least 20 foot-candles of light in all working areas. This shall apply to all rooms where milk or milk products are handled, processed or stored, or where utensils, containers and/or equipment are washed. Dry storage and cold storage rooms shall be provided with at least 5 foot-candles of light.
2. Ventilation in all rooms is sufficient to keep them reasonably free of odors and excessive condensation on equipment, walls and ceilings.
3. Pressurized ventilating systems, if used, have a filtered air intake.

ITEM 5p. SEPARATE ROOMS

There shall be separate rooms for:

1. The pasteurizing, processing, cooling and packaging of milk and milk products.
2. The cleaning of milk cans, bottles and cases.
3. The fabrication of containers and closures for milk and milk products.
4. Cleaning and sanitizing facilities for milk tank trucks in plants receiving milk in such tanks.
5. Receiving cans of milk and milk products in plants receiving such cans.

Rooms in which milk or milk products are handled, processed or stored, or in which milk containers, utensils and equipment are washed or stored, shall not open directly into any stable or any room used for domestic purposes. All rooms shall

be of sufficient size for their intended purposes.

Designated areas or rooms shall be provided for the receiving, handling and storage of returned packaged milk and milk products.

PUBLIC-HEALTH REASON

If the washing and sanitization of containers are conducted in the same room in which the pasteurizing, processing, cooling or packaging is done, there is opportunity for the pasteurized product to become contaminated. For this reason, separate rooms are required as indicated. The unloading of cans of raw milk directly into the pasteurizing room is apt to increase the prevalence of flies therein, as well as to render it too public.

ADMINISTRATIVE PROCEDURES¹¹

This item is deemed to be satisfied when:

¹¹Communities and/or States desiring to regulate cottage cheese, dry curd cottage cheese and reduced fat or low fat cottage cheese under the terms of this Ordinance should include the following in the Administrative Procedures of Item 5p: "Cottage cheese vats shall be located in a separate room, maintained free from flies and other vermin and kept in a clean condition. Provided, that in existing installations, cottage cheese vats may be located in the processing room when there is no evidence of overcrowding, excessive traffic, condensation or splash. Cottage cheese vats located in processing rooms shall be equipped with multi-service or single-service covers which shall be kept in place at all times during the setting operation."

1. Pasteurizing, processing, cooling and packaging are conducted in a single room(s), but not in the same room(s) used for the cleaning of milk cans, bottles and cases, or the unloading and/or cleaning and sanitizing of milk tank trucks. *Provided*, that cooling (plate or tubular) may be done in the room where milk tank trucks are unloaded and/or cleaned and sanitized. Separation/clarification of raw milk may be done in an enclosed room where tank trucks are unloaded and/or cleaned and sanitized.

2. All returned packaged milk and milk products which have physically left the premises of the processing plant shall be received, handled and stored in separate areas or rooms isolated from the Grade "A" dairy operations. Such separate areas or rooms shall be clearly defined and marked for such use.

3. All bulk milk storage tanks are vented into a room used for pasteurization, processing, cooling or packaging operations, or into a storage tank gallery room. *Provided*, that vents located elsewhere which are adequately equipped with air filters so as to preclude the contamination of the milk, shall be considered satisfactory.

4. Facilities for the cleaning and sanitizing of milk tank trucks are properly equipped for manual and/or mechanical operations. When such facilities are not provided on the plant premises, these operations shall be performed at a receiving station, transfer station or separate milk tank truck cleaning facility. (Items relating to facilities for cleaning and sanitizing milk tank trucks are listed at the beginning of this section.

5. Rooms in which milk or milk products are handled, processed or stored, or in which milk containers, utensils and equipment are washed or stored, do not open directly into any stable or any room used for domestic purposes.

6. All rooms shall be of sufficient size for their intended purposes.

ITEM 6p. TOILET-SEWAGE DISPOSAL FACILITIES

Every milk plant shall be provided with toilet facilities conforming with the regulations of the ... of ...¹². Toilet rooms shall not open directly into any room in which milk and/or milk products are processed. Toilet rooms shall be completely enclosed and shall have tight-fitting, self-closing doors. Dressing rooms, toilet rooms and fixtures shall be kept in a clean condition, in good repair and shall be well ventilated and well lighted. Sewage and other liquid wastes shall be disposed of in a sanitary manner.

PUBLIC-HEALTH REASON

Human excreta are potentially dangerous and must be disposed of in a sanitary manner. The organisms causing typhoid fever, para-typhoid fever and dysentery may be present in the body discharges of active cases or carriers. Sanitary toilet facilities are necessary to protect the milk, equipment and containers from fecal contamination which may be carried by flies, other insects, hands or clothing. When the toilet facilities are of a satisfactory type, are kept clean and are in good repair, the opportunities for the spread of contamination by the above means are minimized. The provision of an intervening room or vestibule between the toilet room and any room in which milk or milk products are processed makes it less likely that contaminated flies will enter these

rooms. It will also minimize the spread of odors.

The wastes resulting from the cleaning and rinsing of containers, equipment and floors, from flush toilets, and from washing facilities, should be properly disposed of so as not to contaminate the milk equipment, or to create a nuisance or a public health hazard.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. The milk plant is provided with toilet facilities conforming with the regulations of the ... of ...¹³.

2. Toilet rooms do not open directly into any room in which milk and/or milk products are processed.

3. Toilet rooms are completely enclosed and have tight-fitting, self-closing doors.

4. Dressing rooms, toilet rooms and fixtures are kept in a clean condition, in good repair and are well ventilated and well lighted.

5. Toilet tissue and easily cleanable covered waste receptacles are provided in toilet rooms.

6. All plumbing is installed to meet the applicable provisions of the State or local plumbing code.

7. Sewage and other liquid wastes are disposed of in a sanitary manner.

8. Non-water-carried sewage disposal facilities are not used.

¹² Substitute proper legal jurisdiction here and in all similar places throughout the *Ordinance*.

¹³ Substitute proper legal jurisdiction here and in all similar places throughout the *Ordinance*.

ITEM 7p. WATER SUPPLY

Water for milk plant purposes shall be from a supply properly located, protected and operated and shall be easily accessible, adequate and of a safe, sanitary quality.

PUBLIC-HEALTH REASON

The water supply should be accessible in order to encourage its use in cleaning operations; it should be adequate so that cleaning and rinsing may be thorough; and it should be of a safe, sanitary quality in order to avoid the contamination of milk equipment and containers.

ADMINISTRATIVE PROCEDURES¹⁴

This item is deemed to be satisfied when:

1. Water for milk plant purposes is from an adequate supply, properly located, protected and operated. It shall be easily accessible and of a safe, sanitary quality.

2. The water supply is approved as safe by the State water control authority and, in the case of individual water systems, complies with the specification outlined in Appendix D, and the bacteriological standards outlined in Appendix G.

¹⁴Communities and/or States desiring to regulate cottage cheese, dry curd cottage cheese and reduced fat or lowfat cottage cheese under the terms of this Ordinance should include the following in the Administrative Procedures of Item 7p: "Water supply outlets are provided immediately available to the cottage cheese vats. The hose for transport of water, for washing cottage cheese curd, shall be arranged in such a way as to preclude the possibility of the hose touching the floor or the product."

3. There is no cross-connection between the safe water supply and any unsafe or questionable water supply, or any source of pollution through which the safe water supply might become contaminated. A connection between the water supply piping and a make-up tank (such as for cooling or condensing), unless protected by an air gap or effective backflow preventer, constitutes a violation of this requirement.

4. Condensing water for milk evaporators, and water used to produce vacuum and/or to condense vapors in vacuum heat processing equipment, is from a source complying with 2. above. *Provided*, that when approved by the regulatory agency, water from sources not complying with 2. above may be used when the evaporator or vacuum heat equipment is constructed and operated to preclude contamination of such equipment, or its contents by condensing water or by water used to produce vacuum. Means of preventing such contamination are:

a. Use of a surface type condenser in which the condensing water is physically separated from the vapors and condensate; or

b. Use of reliable safeguards to prevent the overflow of condensing water from the condenser into the evaporator. Such safeguards include a barometric leg extending at least 35 feet vertically from the invert of the outgoing condensing water line to the free level at which the leg discharges, or a safety shutoff valve, located on the water feed line to the condenser, automatically actuated by a control which will shut off the in-flowing water when the water level rises above a predetermined point in the condenser. This valve may be actuated by water, air or electricity, and shall be designed so that failure of the primary motivating power will automatically stop the flow of water into the condenser.

5. Condensing water for all milk evaporators, complying with 2. above, and water reclaimed from milk or milk products may be reused when all necessary means of protection are afforded and it complies with the procedures outlined in Appendix D, Part V.

6. New individual water supplies and water supply systems, which have been repaired or otherwise become contaminated, are disinfected before being placed in use (See Appendix D). The supply shall be made free of the disinfectant by pumping to waste before any sample for bacteriological testing shall be collected.

7. Samples for bacteriological testing of individual water supplies are taken upon the initial approval of the physical structure, each 6 months thereafter and when any repair or alteration of the water supply system has been made. Samples shall be taken by the regulatory agency and examinations shall be conducted in an official laboratory. To determine if water samples have been taken at the frequency established in this section, the interval shall include the designated six month period plus the remaining days of the month in which the sample is due.

8. Current records of water test results are retained on file with the regulatory agency or as the regulatory agency directs.

ITEM 8p. HAND-WASHING FACILITIES

Convenient hand-washing facilities shall be provided, including hot and cold and/or warm running water, soap and individual sanitary towels or other approved hand-drying devices. Hand-washing facilities shall be kept in a clean condition and in good repair.

PUBLIC-HEALTH REASON

Proper use of hand-washing facilities is essential to personal cleanliness and reduces the likelihood of contamination of milk and milk products.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. Convenient hand-washing facilities are provided, including hot and cold and/or warm running water, soap and individual sanitary towels or other approved hand-drying devices.

2. Hand-washing facilities are convenient to all toilets and to all rooms in which milk plant operations are conducted.

3. Hand-washing facilities are kept in a clean condition and in good repair.

4. Steam-water mixing valves and vats for washing bottles, cans and similar equipment are not used as hand-washing facilities.

ITEM 9p. MILK PLANT CLEANLINESS

All rooms in which milk and milk products are handled, processed or stored, and/or in which containers, utensils or equipment are washed or stored, shall be kept clean, neat and free of evidence of insects and rodents. Only equipment directly related to processing operations or the handling of containers, utensils and equipment shall be permitted in the pasteurizing, processing, cooling, packaging and bulk milk storage rooms.

PUBLIC-HEALTH REASON

Clean floors, free of litter, clean walls, ceilings and all other areas of the dairy plant are conducive to clean milk

handling operations. Cleanliness and freedom from flies, insects and rodents reduces the likelihood of contamination of the milk or milk product. Excess or unused equipment or equipment not directly related to the dairy plant operations can be detrimental to the cleanliness of the dairy plant.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. Only equipment directly related to processing operations or the handling of containers, utensils and equipment is permitted in the pasteurizing, processing, cooling, packaging and bulk milk storage rooms.
2. All piping, floors, walls, ceilings, fans, shelves, tables and the non-product-contact surfaces of other facilities and equipment are clean.
3. No trash or solid waste is stored within the plant, except in covered containers. Waste containers at the packaging machine or bottle washer may be uncovered during the operation of such equipment.
4. All rooms in which milk and milk products are handled, processed or stored, and/or in which containers, utensils, or equipment are washed or stored, are kept clean, neat and free of evidence of insects and rodents.

ITEM 10p. SANITARY PIPING

All sanitary piping, fittings and connections which are exposed to milk or milk products, or from which liquids may drip, drain or be drawn into milk or milk products, shall consist of smooth, impervious, corrosion-resistant, nontoxic, easily cleanable material which is approved for food contact surfaces. All piping shall be in good repair. Pasteurized milk and milk products shall be conducted from one piece

of equipment to another only through sanitary piping.¹⁵

PUBLIC-HEALTH REASON

Milk piping and fittings are sometimes so designed as to be difficult to clean, or they may be constructed of metal which corrodes easily. In either case, it is unlikely that they will be kept clean. Sanitary milk piping is a term which applies to properly designed and properly constructed piping.

The purpose of the third sentence is to prevent exposure of the pasteurized product to contamination.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. All sanitary piping, fittings and connections which are exposed to milk or milk products, or from which liquids may drip, drain or be drawn into milk products, consist of smooth, impervious, corrosion-resistant, nontoxic, easily cleanable material.
2. All sanitary piping, connections and fittings consist of:
 - a. Stainless steel of the AISI (American Iron and Steel Institute) 300 series; or
 - b. Equally corrosion-resistant metal which is nontoxic and nonabsorbent; or

¹⁵ Communities and/or States desiring to regulate cottage cheese, dry curd cottage cheese and reduced fat or lowfat cottage cheese under the terms of this *Ordinance* should add the following: "*Provided*, that cottage cheese, cheese dressings or cheese ingredients may be transported by other methods which protect the product from contamination."

c. Heat resistant glass; or
d. Plastic, or rubber and rubber-like materials which are relatively inert, resistant to scratching, scoring, decomposition, crazing, chipping and distortion under normal use conditions; are nontoxic, fat resistant, relatively nonabsorbent; which do not impart flavor or odor to the product; and which maintain their original properties under repeated use conditions, may be used for gaskets, sealing applications and for short flexible takedown jumpers or connections where flexibility is required for essential or functional reasons.

3. Sanitary piping, fittings and connections are designed to permit easy cleaning, kept in good repair and free of breaks or corrosion, and contain no dead ends of piping in which milk may collect.

4. All interior surfaces of demountable piping, including valves, fittings and connections are designed, constructed and installed to permit inspection and drainage.

5. All mechanically cleaned milk pipelines and return-solution lines are rigid, self-draining and so supported to maintain uniform slope and alignment. Return solution lines shall be constructed of material meeting the specifications of 2. above. If gaskets are used, they shall be self-positioning, of material meeting the specifications outlined in 2. above and designed, finished and applied to form a smooth, flush interior surface. If gaskets are not used, all fittings shall have self-positioning faces designed to form a smooth, flush interior surface. All interior surfaces of welded joints in pipelines shall be smooth and free from pits, cracks or inclusions.

In the case of welded lines, all welds shall be inspected as they are made and such welds shall be approved by the regulatory agency.

Each cleaning circuit shall have access points for inspection in addition to

the entrances and exits. These may be valves, removable sections, fittings or other means of combinations that are adequate for the inspection of the interior of the line. These access points shall be located at sufficient intervals to determine the general condition of the interior surfaces of the pipeline.

Detailed plans for welded pipeline systems shall be submitted to the regulatory agency for written approval prior to installation. No alteration or addition shall be made to any welded milk pipeline system without prior written approval from the regulatory agency.

6. Pasteurized milk and milk products are conducted from one piece of equipment to another only through sanitary milk piping.

ITEM 11p. CONSTRUCTION AND REPAIR OF CONTAINERS AND EQUIPMENT

All multi-use containers and equipment with which milk or milk products come into contact shall be of smooth, impervious, corrosion-resistant, nontoxic material; shall be constructed for ease of cleaning; and shall be kept in good repair. All single-service containers, closures, gaskets and other articles with which milk or milk products come in contact shall be nontoxic and shall have been manufactured, packaged, transported and handled in a sanitary manner. Articles intended for single-service use shall not be reused.

PUBLIC-HEALTH REASON

When equipment is not constructed and located so that it can be cleaned easily, and which is not kept in good repair, it is unlikely that it will be properly cleaned.

Single-service articles, which have not been manufactured and handled in a sanitary manner may contaminate the milk.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. All multi-use containers and equipment with which milk or milk products come into contact are of smooth, impervious, corrosion-resistant and nontoxic material.

2. All milk-contact surfaces of multi-use containers and equipment consist of:

a. Stainless steel of the AISI (American Iron and Steel Institute) 300 series; or

b. Equally corrosion-resistant metal which is nontoxic and nonabsorbent; or

c. Heat resistant glass; or

d. Plastic or rubber and rubber-like materials which are relatively inert, resistant to scratching, scoring, decomposition, crazing, chipping and distortion under normal use conditions; which are nontoxic, fat resistant, relatively nonabsorbent and do not impart flavor or odor to the product; and which maintain their original properties under repeated use conditions.

3. All joints in containers, equipment and utensils are flush and finished as smooth as adjoining surfaces. Where a rotating shaft is inserted through a surface with which milk or milk products come into contact, the joint between the moving and stationary surfaces shall be close-fitting. Where a thermometer or temperature sensing element is inserted through a surface, with which milk or milk products come into contact, a pressure-tight seal shall be provided ahead of all threads and crevices.

4. All openings in covers of tanks, vats, separators, etc. are protected by raised edges, or otherwise, to prevent the entrance of surface drainage. Condensation-diverting aprons shall be provided as close to the tank or vat as possible on all pipes, thermometers, or temperature sensing elements and other equipment extending into a tank, bowl, vat or distributor, unless a watertight joint is provided.

5. All surfaces with which milk or milk products come into contact are easily accessible or demountable for manual cleaning or are designed for mechanical cleaning. All product-contact surfaces shall be readily accessible for inspection and shall be self-draining.

6. There are no threads used in contact with milk or milk products except where needed for functional and safety reasons, such as in clarifiers, pumps and separators. Such threads shall be of a sanitary type.

7. All multi-use containers and other equipment have rounded corners, are in good repair and free from breaks, crevices and corrosion. Milk cans shall have umbrella-type covers.

8. Strainers, if used, are of perforated metal design and so constructed as to utilize single-service strainer media. Multiple-use, woven material shall not be used for straining milk. *Provided*, that when required for functional reasons inherent to the production of certain milk products, such as buttermilk, whey and dry milk products, woven material may be used where it is impractical to use perforated metal. However, woven material parts shall be mechanically cleaned by such methods that thoroughly clean the woven material and do not contaminate the product.

9. All single-service containers, closures, gaskets and other articles, with which milk or milk products come in contact, are nontoxic.

10. The manufacture, packing, transportation and handling of single-service containers, closures, caps, gaskets and similar articles comply with the requirements of Appendix J, Standards for the Fabrication of Single-Service Containers and Closures for Milk and Milk Products. Inspections and tests shall be made by the regulatory agency or any agency authorized by them.

NOTE: *3-A Sanitary Standards:* 3-A Sanitary Standards for dairy equipment are promulgated jointly by the Sanitary Standards Subcommittee of the Dairy Industry Committee, the Committee on Sanitary Procedure of the International Association for Food Protection and the Milk Safety Branch, Center for Food Safety and Applied Nutrition, Food and Drug Administration, Public Health Service, Department of Health and Human Services. Equipment manufactured in conformity with 3-A Sanitary Standards complies with the sanitary design and construction standards of this *Ordinance*.

ITEM 12p. CLEANING AND SANITIZING OF CONTAINERS AND EQUIPMENT

The product-contact surfaces of all multi-use containers, utensils and equipment used in the transportation, processing, handling and storage of milk or milk products shall be effectively cleaned and shall be sanitized before each use. *Provided*, that piping, equipment and containers used to process, conduct or package aseptically processed milk and milk products, beyond the final heat treatment process, shall be sterilized before any aseptically processed milk or milk product is packaged and shall be resterilized whenever any unsterile product has contaminated it.

PUBLIC-HEALTH REASON

Milk and milk products cannot be kept clean and safe, if permitted to come into contact with containers, utensils and equipment which have not been properly cleaned and sanitized.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. All multi-use containers and utensils are thoroughly cleaned after each use and all equipment is thoroughly cleaned at least once each day used unless the FDA and the state dairy regulatory authority have reviewed and accepted information supporting the cleaning of multi-use containers and utensils at frequencies extending beyond one day. *Provided*, that storage tanks shall be cleaned when emptied and shall be emptied at least every 72 hours. Records must be available to verify that milk storage in these tanks does not exceed 72 hours. These records shall be available for at least the previous 3 months or from the time of the last regulatory inspection whichever is longer. In the case of pasteurized storage tanks which are mechanically cleaned at intervals of less than 72 hours, the mechanical cleaning records required under 2.b. of this section shall be considered adequate. Storage tanks which are used to store raw milk or heat-treated milk products longer than 24 hours and silo tanks used for the storage of raw milk or heat-treated milk products shall be equipped with a 7-day temperature recording device complying with the specifications of Appendix H.

Whenever a milk tank truck has been cleaned and sanitized, as required by the regulatory agency, it shall bear a tag or a record shall be made showing the date, time,

place and signature or initials of the employee or contract operator doing the work, unless the truck delivers to only one receiving unit where responsibility for cleaning and sanitizing can be definitely established without tagging. The tag shall be removed at the location where the tank truck is next washed and sanitized and kept on file for 15 days as directed by the regulatory agency.

2. Pipelines and/or equipment designed for mechanical cleaning meet the following requirements:

a. An effective cleaning and sanitizing regimen for each separate cleaning circuit shall be followed.

b. A temperature recording device, complying with the specifications in Appendix H, or a recording device which provides sufficient information to adequately evaluate the cleaning and sanitizing regimen and which is approved by the local regulatory agency, shall be installed in the return solution line or other appropriate area to record the temperature and time which the line or equipment is exposed to cleaning and sanitizing solutions. For purposes of this section, recording devices which produce records not meeting the specifications of Appendix H may be acceptable if;

(1) The device provides a continuous record of the monitoring of the cleaning cycle time and temperature, cleaning solution velocity or cleaning pump operation and the presence or strength of cleaning chemicals for each cleaning cycle.

(2) The record shows a pattern so typical of each circuit cleaned that changes

in the cleaning regimen can be readily detected.

(3) Electronic storage of required cleaning records with or without hard copy printouts may be acceptable provided the computer and computer generated records are readily available and meet the criteria of this section and those provisions of Appendix H which are determined to be applicable by the regulatory agency and FDA.

c. Cleaning charts and electronically stored records required by this section shall be identified, dated and retained for 3 months or until the next regulatory inspection, whichever is longer.

d. During each official inspection, the regulatory agency shall examine charts and records to verify the cleaning regimens.

3. Plants in which containers are washed manually are equipped with a two-compartment wash-and-rinse vat for this purpose. Such plants shall also provide a steam cabinet or individual steam-jet plate with hood for sanitizing of cleaned containers, or if sanitizing is done with chemicals, a third treatment vat.

4. In plants utilizing automatic bottle washers, such washers must provide for bactericidal treatment by means of steam, hot water or chemical treatment. In soaker-type bottle washers, in which bactericidal treatment depends upon the causticity of the washing solution, the caustic strength for a given soaking time and temperature shall be as specified in the following table which lists the combinations of causticity, time and temperature, of equal bactericidal value, for the soaker tank of soaker-type bottle washers:

Table 2. Combinations of Causticity, Time and Temperature, of Equal Bactericidal Value, for the Soaker Tank of Soaker Type Bottle Washers

(Based on NSDA Specifications for beverage bottles.

	Temperature, Degrees							
	C	77	71	66	60	54	49	43
	F	170	160	150	140	130	120	110
Time in Minutes	Concentration of NaOH (percent)							
3	0.57	0.86	1.28	1.91	2.86	4.27	6.39	
5	0.43	0.64	0.96	1.43	2.16	3.22	4.80	
7	0.36	0.53	0.80	1.19	1.78	2.66	3.98	

NOTE: The National Soft Drink Association (NSDA), Washington, D.C. 20036 alkali test, the NSDA caustic test, or other suitable test may be used to determine the strength of the soaker solution. The caustic strength shall be tested monthly by the regulatory agency.

When caustic is so used, subsequent final rinsing of the bottles shall be with water which has been treated with heat or chemicals to assure freedom from viable pathogenic or otherwise harmful organisms, to prevent recontamination of the treated bottle during the rinsing operation.

5. All multi-use containers, equipment and utensils are sanitized before use, employing one or a combination of the methods prescribed under Item 11r. Assembled equipment must be sanitized prior to each day's run, unless the FDA and the state dairy regulatory authority have reviewed and accepted information supporting the sanitizing of multi-use containers, equipment and utensils at frequencies extending beyond one day. Tests to determine the efficiency of sanitization should be made by the regulatory agency at intervals sufficient to satisfy the regulatory agency that the sanitization process is effective. Provided, that all piping, equipment and containers used to conduct, process or package aseptically

processed milk and milk products, beyond the final heat treatment process, shall be sterilized by heat, chemical sterilant(s) or other appropriate treatment before use and resterilized whenever it has been contaminated by unsterile product.

6. a. The residual bacteria count of multi-use containers and closures shall be conducted as outlined in Appendix J. The residual bacteria count of multi-use containers, used for packaging pasteurized milk and milk products, shall not exceed one organism per milliliter of capacity, when the rinse test is used, or not over 50 colonies per 50 square centimeters (one colony per square centimeter) of product-contact surface, when the swab test is used, in 3-out-of-4 samples taken at random on a given day. All multi-use containers shall be free of coliform organisms.

b. The residual bacteria count of single-service containers and closures, used for packaging pasteurized milk and milk products, shall not exceed 50 per container, when the rinse test is used, except that in

containers less than 100 ml, the count shall not exceed 10 or not over 50 colonies per 8 square inch (1 per square centimeter) of product-contact surface, when the swab test is used, in 3-out-of-4 samples taken at random on a given day. All single-service containers shall be free of coliform organisms.

When single-service containers or closures are fabricated in another plant which conforms to the Standards of Appendix J, and the regulatory agency has information that they do comply, the regulatory agency may accept the containers as being in conformance without additional tests. If there is reason to believe that containers do not conform to the bacteriological standards, additional tests may be required. If containers are fabricated in the dairy plant, the regulatory agency shall collect at least 4 sets of containers, each 6 months, and determine conformance.

7. Plants which utilize multi-use plastic containers, for pasteurized milk and milk products, shall comply with the following criteria:

a. All containers shall be identified as to plant of manufacture, date of manufacture and type and class of plastic material used. This information may be by code. *Provided*, that the code is revealed to the regulatory agency.

b. A device shall be installed in the filling line capable of detecting, in each container before it is filled, volatile organic contaminants in amounts that are of public health significance. Such device must be constructed so that it may be sealed by the regulatory agency to prevent the changing of its sensitivity functioning level. Models using an air injection system and with a testing device built into the detection equipment do not have to be sealed. To assure proper functioning of the system the operator needs to be able to adjust the sensitivity. However, those models utilizing an

external testing device must be sealed. Any container detected by the device as being unsatisfactory must be automatically made unusable to prevent refilling. In addition, the device must be interconnected so that the system will not operate unless the detecting device is in proper operating condition. *Provided*, that any other system so designed and operated that will provide equal assurance of freedom from contamination and recognized by the Food and Drug Administration to be equally efficient may be accepted by the regulatory agency.

c. A standard must be available for use by the regulatory agency for testing the proper sensitivity functioning levels of the detection device.

d. The containers shall comply with the applicable construction requirements of Item 11p. of this *Ordinance*. The closure for the container shall be single-service. Screw-type closures shall not be used.

e. The container shall not impart, into the product, pesticide residual levels or other chemical contaminants in excess of those considered acceptable under the *Federal Food, Drug, and Cosmetic Act*, as amended and regulations issued thereunder.

f. The phrase "Use only for food" shall appear on all containers.

ITEM 13p. STORAGE OF CLEANED CONTAINERS AND EQUIPMENT

After cleaning, all multi-use milk or milk product containers, utensils and equipment shall be transported and stored to assure complete drainage and shall be protected from contamination before use.

PUBLIC-HEALTH REASON

If containers and equipment are not protected from contamination, the value of sanitization may be partly or entirely nullified.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

All multi-use containers, equipment and utensils, after cleaning, are transported and/or stored on racks made of impervious food grade materials, or in clean cases elevated above the floor. Containers shall be stored inverted on racks or in cases constructed of relatively nonabsorbent, impervious, food-grade, corrosion-resistant, nontoxic materials, or otherwise protected from contamination.

ITEM 14p. STORAGE OF SINGLE-SERVICE CONTAINERS, UTENSILS AND MATERIALS

Single-service caps, cap stock, parchment paper, containers, gaskets and other single-service articles for use in contact with milk and milk products shall be purchased and stored in sanitary tubes, wrappings or cartons; shall be kept therein in a clean, dry place until used; and shall be handled in a sanitary manner.

PUBLIC-HEALTH REASON

Soiled or contaminated caps, parchment paper, gaskets and single-service containers nullify the benefits of the safeguards prescribed throughout the *Ordinance*. Packing the caps in tubes which remain unbroken until they are placed in the bottling machine is the best method of assuring cap cleanliness.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. Single-service caps, cap stock, parchment paper, containers, gaskets and other single-service articles for use in contact with milk and milk products are purchased and stored in sanitary tubes, wrappings or cartons; are kept in a clean, dry place until used; and are handled in a sanitary manner.

2. Paperboard shipping containers used to enclose plastic bags or unfilled containers are used only once unless other methods are employed to protect the containers from contamination.

3. Tubes or cartons are not refilled with spilled caps, gaskets or parchment papers.

4. Cartons or boxes from which contents have been partially removed are kept closed.

5. Suitable cabinets are provided for storage of tubes after removal from the large outer box, and for storage of opened cartons, unless other satisfactory means are employed to protect the caps, closures or containers.

ITEM 15p. PROTECTION FROM CONTAMINATION

Milk plant operations, equipment and facilities shall be located and conducted to prevent any contamination of milk or milk products, ingredients, equipment, containers and utensils. All milk or milk products or ingredients which have been spilled, overflowed or leaked shall be discarded. The processing or handling of products other than milk or milk products in the pasteurization plant shall be performed to preclude the contamination of such milk and milk products. The storage, handling and use of poisonous or toxic materials shall be performed to preclude the contamination of milk and milk products, or ingredients of such milk and milk products or the product-contact surfaces of all equipment, containers or utensils.

PUBLIC-HEALTH REASON

Because of the nature of milk and milk products and their susceptibility to contamination by bacteria, chemicals and other adulterants, every effort should be made to provide adequate protection for the milk and milk products at all times. Misuse of pesticides and other harmful chemicals can provide opportunities for contamination of the milk, milk product or equipment with which the milk or milk product comes in contact.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

15p(A).

1. Equipment and operations are so located within the plant as to prevent overcrowding and contamination of cleaned and sanitized containers, equipment and utensils by splash, condensation or manual contact.

2. Packaged milk and milk products which have physically left the premises or the processing plant are not repasteurized for Grade "A" use. The regulatory agency may, on a specific individual request, authorize reprocessing of packaged milk and milk products, provided all other aspects of this item, including proper storage temperature and container integrity are complied with. *Provided*, that the repasteurization of milk and milk products shipped in transport milk tank trucks which have been pasteurized at another Grade "A" plant and have been handled in a sanitary manner and maintained at 7°C (45°F) or less is permitted. Equipment, designated areas or rooms utilized for storage, processing and handling of returned packaged milk and milk products are maintained, operated, cleaned and sanitized so as to preclude contamination of Grade "A" products and equipment and the Grade "A" operations.

3. All product-contact surfaces of containers, equipment and utensils are covered or otherwise protected to prevent the access of insects, dust, condensation and other contamination. All openings, including valves and piping attached to milk storage and milk tank trucks, pumps, vats, etc., shall be capped or otherwise properly protected. While unloading at a pasteurization plant, receiving station or

transfer station, one of the following conditions shall be met:

a. If the area is completely enclosed (walls and ceiling, with doors closed) during the unloading process and the dust-cover or dome and the manhole cover is opened slightly and held in this position by the metal clamps used to close the cover, then a filter is not required. However, if the dust-cover and/or manhole cover(s) are opened in excess of that provided by the metal clamps or the covers have been removed, then a suitable filter is required for the manhole.

b. If the area is not completely enclosed or doors of the unloading area are open during unloading, a suitable filter is required for the manhole or air inlet vent and suitable protection must be provided over the filter material either by design of the filter holding apparatus or a roof or ceiling over the area. When weather and environmental conditions permit, manhole openings and covers of milk tank trucks may be opened outdoors for the short period of time necessary for the collection of samples for animal drug residue screening. Direct connections from milk tank truck to milk tank truck must be made from valve to valve or through the manhole lid. *Provided*, that all connections are made ferrule to ferrule and adequate protection is provided for the air vent.

Receiving and dump vats shall be completely covered, except during washing and sanitizing, and when milk is being dumped. Where strainers are used, the cover for the vat opening shall be designed to cover the opening with the strainer in place.

4. Whenever air under pressure is used for the agitation or movement of milk, or is directed at a milk-contact surface, it is free of oil, dust, rust, excessive moisture, extraneous materials and odor, and shall otherwise comply with the applicable standards of Appendix H. The use of steam

containing toxic substances is expressly prohibited. Whenever steam is used in contact with milk or milk products, it shall be of culinary quality and shall comply with the applicable standards of Appendix H.

5. Standardization of Grade "A" milk and milk products with other than Grade "A" milk and milk products is prohibited. This *Ordinance* permits standardization as a process of adjusting the milkfat of milk in a milk plant by the addition or removal of cream or non-fat (skim) milk.

6. All multi-use cases used to encase packaged milk and milk product containers are cleaned prior to their use.

7. All ingredients and non-product-contact materials used in the preparation or packaging of milk and milk products are stored in a clean place and are so handled as to prevent their contamination.

8. Pasteurized milk is not strained or filtered except through a perforated metal strainer.

9. Only those poisonous or toxic materials, including but not limited to insecticides, rodenticides, detergents, sanitizers, caustics, acids, related cleaning compounds and medicinal agents necessary for the maintenance of the dairy plant are present in the dairy plant.

10. Those poisonous or toxic materials that are necessary are not stored in any room where milk or milk products are received, processed, pasteurized or stored; or where equipment, containers or utensils are washed; or where single-service containers, closures or caps are stored.

11. Those poisonous or toxic materials that are necessary are stored in a separate area of the plant in prominently and distinctly labeled containers. *Provided* that, this does not preclude the convenient availability of detergents or sanitizers to areas where equipment, containers, and utensils are washed and sanitized.

12. Only insecticides and rodenticides approved by the regulatory agency and/or registered with the U.S. Environmental Protection Agency shall be used for insect and rodent control. Such insecticides and rodenticides shall be used only in accordance with the manufacturer's label directions and shall be prevented from contaminating milk, containers, equipment and utensils.

13. In the case of separating non-Grade "A" and Grade "A" products, a water rinse after processing non-Grade "A" and prior to Grade "A" is adequate separation, provided both are processed as Grade "A" and raw and pasteurized products are kept physically separated.

14. Grade "A" raw milk or milk products and non-Grade "A" raw products (dairy or non-dairy) shall be separated by one valve.

15. Grade "A" pasteurized milk or milk products and non-Grade "A" pasteurized products (dairy or non-dairy) shall be separated by one valve.

16. Except during the actual flushing of raw product lines and vessels with water, there shall be a sufficient separation between water piping and unpasteurized dairy products, or lines used to conduct unpasteurized dairy products, to prevent the accidental addition of water.

15p(B)

1. During processing, pipelines and equipment used to contain or conduct milk and milk products shall be effectively separated from tanks or circuits containing cleaning, and/or sanitizing solutions. This can be accomplished by:

a. Physically disconnecting all connection points between tanks or circuits containing cleaning and/or sanitizing solutions from pipelines and equipment used

to contain or conduct milk or milk products, or

b. Separation of all connection points between such circuits by at least two automatically controlled valves with a drainable opening to the atmosphere between the valves, or by a single bodied double seat valve, with a drainable opening to the atmosphere between the seats, if:

(1) The opening to the atmosphere (vent) is equal to the largest pipeline feeding the valve(s).

(2) Both valves (or valve seats in the case of single bodied double seat valves) are position detectable, and capable of providing an electronic signal when not properly seated in the blocked position.

(3) These valves (or valve seats in the case of single bodied double seat valves) are part of an automatic failsafe system which will prevent contamination of product with cleaning or sanitizing solutions. Automatic fail safe systems will be unique to each particular installation but are normally based on the premise that both blocking valve seats are properly seated in the blocked position before the mechanical cleaning system can be activated for the cleaning circuit containing this valve arrangement.

(4) The system does not have any manual overrides.

(5) Controls for the fail safe system are secured as directed by the regulatory agency in order to prevent unauthorized changes.

(6) The vent is not cleaned until milk and milk products have been removed or isolated.

(7) Variations from the above specifications may be individually evaluated and found to also be acceptable if the level of protection is not compromised.

For example: In low pressure, gravity drain applications where the product line is the

same size or larger than the cleaning or sanitizing solution line; the vent may be the size of the solution line and the valves or valve seats need not be position detectable (all other criteria still apply). In order to accept this variation, the valve(s) must fail to the blocked position upon loss of air or power, and there must be no pumps capable of pushing milk, milk product, cleaning solutions, or sanitizing solutions into this valve arrangement.

IMPORTANT NOTE: The valve arrangement(s) described in this section shall not be used to separate raw products (dairy, non-dairy or water) from pasteurized milk or milk products.

2. Except as permitted in 16p there shall be no physical connection between unpasteurized products (dairy, non-dairy, or water) and pasteurized milk or milk products. Pasteurized non-dairy products or water not completely separated from pasteurized dairy products, shall be pasteurized at times and temperatures which meet at least the minimum times and temperatures provided for in Definition V or in the case of water have undergone an equivalent process found acceptable by FDA and the State Regulatory Authority.

This section does not require separate raw and pasteurized mechanical cleaning systems.

3. Pasteurized re-circulation lines, divert lines, and leak detect lines connecting to the raw product constant level supply tank shall be designed so that there is an air gap between the termination of these pipelines and the raw product overflow level. This air gap must be equivalent to at least two times the diameter of the largest of these pipelines. For purposes of this section an overflow is defined as the flood rim of the constant level supply tank or any unrestricted opening below the flood rim of the constant level

supply tank which is large enough that it is at least equivalent to two times the diameter of the largest of these pipelines.

4. All milk and milk products which have overflowed, leaked, been spilled or improperly handled are discarded. Milk and milk products drained from processing equipment at the end of a run, collected from a defoamer system and milk solids rinsed from equipment, containers or pipelines shall be repasteurized only if such milk and milk products are handled in a sanitary manner and maintained at 7°C (45°F) or less. When the handling and/or refrigeration of such milk and milk products are not in compliance with this requirement, they shall be discarded. Milk and milk products from damaged, punctured or otherwise contaminated containers or product from out of code containers shall not be repasteurized for Grade "A" use.

5. Means are provided to prevent contamination of milk containers, utensils and equipment by drippings, spillage and splash from overhead piping, platforms or mezzanines.

6. The processing of foods and/or drinks other than Grade "A" milk and milk products are performed to preclude the contamination of such milk and milk products.

7. In no case shall pasteurized milk or milk products be standardized with unpasteurized milk unless the standardized product is subsequently pasteurized.

8. Reconstituted or recombined milk and milk products shall be pasteurized after reconstitution or recombining of all ingredients.

ITEM 16p. PASTEURIZATION AND ASEPTIC PROCESSING

Pasteurization shall be performed as defined in Section 1, Definition V of this *Ordinance*. Aseptic processing shall be performed in accordance with 21 CFR 113, (See Appendix L), 21 CFR 108 and the Administrative Procedures of Item 16p, C, D and E of this section.

PUBLIC-HEALTH REASON

The public health value of pasteurization is unanimously agreed upon by health officials. Long experience conclusively shows its value in the prevention of disease which may be transmitted through milk. Pasteurization is the only practical, commercial measure which, if properly applied to all milk, will destroy all milkborne disease organisms. Examination of lactating animals and milk handlers, while desirable and of great value, can be done only at intervals and; therefore, it is possible for pathogenic bacteria to enter the milk for varying periods before the disease condition is discovered. Disease bacteria may also enter milk accidentally from other sources, such as flies, contaminated water, utensils, etc. It has been demonstrated that the time-temperature combinations specified by this *Ordinance*, if applied to every particle of milk, will devitalize all milkborne pathogens. Compilations of outbreaks of milkborne disease by the U.S. Public Health Service, over many years, indicate that the risk of contracting disease from raw milk is approximately 50 times as great as from milk labeled "pasteurized".

A note of caution is in order. Although pasteurization devitalizes the organisms, it does not destroy the toxins that may be formed in milk when certain staphylococci are present (as from udder

infections) and when the milk is not properly refrigerated before pasteurization. Such toxins may cause severe illness.

Numerous studies and observations clearly prove that the food value of milk is not significantly impaired by pasteurization.

ADMINISTRATIVE PROCEDURES

The pasteurization portion of this item is deemed to be satisfied when:

1. Every particle of milk or milk product is heated in properly designed and operated equipment to one of the temperatures specified in the following table and held continuously at or above that temperature for at least the time specified:

Table 3. Pasteurization Temperature vs. Time	
Temperature	Time
*63°C (145°F)	30 minutes
*72°C (161°F)	15 seconds
89°C (191°F)	1.0 second
90°C (194°F)	0.5 second
94°C (201°F)	0.1 second
96°C (204°F)	0.05 second
100°C (212°F)	0.01 second
*If the fat content of the milk product is 10 percent or more, or if it contains added sweeteners, the specified temperature shall be increased by 3°C (5°F). <i>Provided</i> , that eggnog shall be heated to at least the following temperature and time specifications:	
69°C (155°F)	30 minutes
80°C (175°F)	25 seconds
83°C (180°F)	15 seconds
<i>Provided further</i> , that nothing shall be construed as barring any other pasteurization process which has been recognized by the Food and Drug Administration to be equally efficient and which is approved by the regulatory agency.	

2. The design and the operation of pasteurization equipment and all appurtenances thereto shall comply with the applicable specifications and operational procedures of subitems (A), (B), (D) and (E) as follows:

ITEM 16p(A). BATCH PASTEURIZATION

All indicating and recording thermometers used in connection with the batch pasteurization of milk or milk products shall comply with the applicable specifications set forth in Appendix H. Specification for test thermometer and other test equipment appear in Appendix I.

PUBLIC-HEALTH REASON

Unless the temperature-control instruments and devices used on pasteurization equipment are accurate within known limits, there can be no assurance that the proper pasteurization temperature is being applied. Pasteurization must be performed in equipment which is properly designed and operated and which insures that every particle of milk or milk products will be held continuously at the proper temperature for the specified period of time.

Recording thermometers are the only known means for furnishing the regulatory agency with a record of the time and temperature of pasteurization. Experience has shown that recording thermometers, due to their mechanical complexity, are not entirely reliable. Therefore, mercury indicating thermometers, which are much more reliable, are needed to provide a check on the recording thermometer and assurance that proper temperatures are being applied.

The recording thermometer shows the temperature of the milk immediately surrounding its bulb, but cannot indicate the temperature of the milk in other portions of the holder. Similarly, it shows the holding time in manual-discharge vats, but not in automatic-discharge systems. The pasteurizer must; therefore, be so designed and so operated and, where necessary, provided with such automatic controls, as to assure that every portion of the milk will be subjected to the proper temperature for the required length of time.

Unless the inlet and outlet valves and connections to the vats and pockets are properly designed and operated, cold pockets of milk may be held in the outlet valve or pipeline; raw milk may leak into the vat or pocket during the holding or emptying time; and raw or incompletely pasteurized milk

may leak into the outlet line during the filling, heating or holding period.

Tests have shown that when foam is present on milk in vats or pockets during pasteurization, the temperature of the foam may be well below the pasteurization temperature. In such cases, pathogenic organisms, that may be in the foam, will not be killed. Experience indicates that some foam is present at some time in all vats, particularly at certain seasons. Furthermore, in filling vats, milk frequently is splashed on the surfaces and fixtures above the milk level, as well as on the underside of the vat cover. Droplets of this splash may drop back into the body of the milk, and since they may not have been at pasteurization temperature for the required time, they may contain living pathogenic organisms. Heating the air above the milk, above pasteurization temperature, remedies these conditions. When air heating is not provided, its need may frequently be demonstrated by swabbing milk from the upper vat walls and from the underside of the cover, at the end of the holding period, and running phosphatase tests on the swab samples.

Many plant operators have reported that the use of airspace heaters, especially with partly filled vats with un-insulated lids, makes it easier to maintain the milk at a uniform and sufficiently high temperature. It also helps to prevent the growth of thermophilic organisms and promotes easier cleaning.

Obviously, if the design and construction of pasteurization vats and pocket covers do not prevent leakage, condensation and the entrance of water and dust, the milk may become contaminated with material containing disease bacteria. Keeping the covers closed during operation will decrease the chance of dust, flies, sputum droplets, drip and splash entering the milk.

ADMINISTRATIVE PROCEDURES

1. TIME AND TEMPERATURE CONTROLS FOR BATCH PASTEURIZERS:

a. **Temperature Difference:** The pasteurizer shall be so designed that the simultaneous temperature difference between the milk or milk product, at the center of the coldest milk or milk product in the vat, will not exceed 0.5°C (1°F) at any time during the holding period.

The vat shall be provided with adequate agitation, operating throughout the holding period. No batch of milk or milk product shall be pasteurized unless it covers a sufficient area of the agitator to insure adequate agitation.

b. **Location and Required Readings of Indicating and Recording Thermometers:** Each batch pasteurizer shall be equipped with both an indicating and a recording thermometer.

The thermometer shall read not less than the required pasteurization temperature throughout the required holding period. The plant operator shall check the temperature shown by the recording thermometer against the temperature shown by the indicating thermometer at the start of the holding period. This comparison shall be noted on the recording thermometer chart. The recording thermometer shall not read higher than the indicating thermometer. No batch of milk or milk products shall be pasteurized unless it is sufficient to cover the bulbs of both the indicating and the recording thermometer.

c. **Assurance of Minimum Holding Periods:** Batch pasteurizers shall be so operated that every particle of milk or milk product will be held at not less than the minimum pasteurization temperature continuously for at least 30 minutes. When milk or milk products are raised to

pasteurization temperature in the vat, and cooling is begun in the vat simultaneously with or before the opening of the outlet valve, the recorder chart shall show at least 30 minutes, at not less than minimum pasteurization temperature. When milk or milk products are preheated to pasteurization temperature before entering the vat, the recorder chart shall show a holding period of at least 30 minutes, at not less than the minimum pasteurization temperature plus the time of filling from the level of the recorder bulb. When cooling is begun in the holder, after the opening of the outlet valve or is done entirely outside the holder, the chart shall show at least 30 minutes at not less than the minimum pasteurization temperature plus the time of emptying to the level of the recording-thermometer bulb.

When the recorder time interval on the recorder chart at the pasteurization temperature includes filling and/or emptying time, such intervals shall be indicated on the recorder chart, by the operator, by removing the recording-thermometer bulb from the milk for a sufficient time to depress the pen; or by turning cold water into the vat jacket at the end of the holding period; or by inscribing the holding time on the chart. The filling time and the emptying time for each holder, so operated, shall be determined by the regulatory agency, initially and after any change which may affect these times.

No milk shall be added to the holder after the start of the holding period.

2. AIRSPACE HEATING:

a. Means shall be provided and used in batch pasteurizers to keep the atmosphere above the milk and milk products at a temperature not less than 3°C (5°F) higher than the minimum required temperature of pasteurization, during the holding period (Appendix H).

b. Each batch pasteurizer shall be equipped with an airspace thermometer. The surface of the milk or milk product shall be at least 25 millimeters (1 inch) below the bottom of the thermometer bulb when the vat is in operation.

c. The temperature shown by the airspace thermometer shall be recorded on the recording thermometer chart at the start of the holding period and at the end of the holding period, at a given time or reference point as indicated on the chart.

3. INLET AND OUTLET VALVES AND CONNECTIONS:

The following definitions shall apply to inlet and outlet valves and connections:

a. **"Valve stop"** shall mean a guide which permits turning the valve plug to, but not beyond, the fully closed position.

b. **"The fully open position"** shall mean that position of the valve seat which permits the maximum flow into or out of the pasteurizer.

c. **"The closed position"** shall mean any position of the valve seat which stops the flow of milk into or out of the pasteurizer.

d. **"The fully closed position"** shall mean that closed position of the valve seat which requires the maximum movement of the valve to reach the fully open position.

e. **"The just-closed position"** shall mean that closed position of a plug-type valve in which the flow into or out of the holder is barely stopped, or any position within 2 millimeters (0.078 inch) thereof as measured along the maximum circumference of the valve seat.

f. **"Leakage"** shall mean the entrance of unpasteurized milk into a batch pasteurizer during the holding or emptying

period, or the entrance of unpasteurized milk into any pasteurized milk line at any time.

g. **"Leak-protector valve"** shall mean a valve provided with a leak-diverting device, which, when the valve is in any closed position, will prevent leakage of milk past the valve.

h. **"Close-coupled valve"** shall mean a valve, the seat of which is either flush with the inner wall of the pasteurizer or so closely coupled that no milk in the valve inlet is more than 0.5°C (1°F) colder than the milk at the center of the pasteurizer at any time during the holding period.

A close-coupled valve which is not truly flush, shall be considered as satisfying this requirement when:

(1) The vat outlet is so flared that the smallest diameter of the large end of the flare is not less than the diameter of the outlet line, plus the depth of the flare; and

(2) The greatest distance from the valve seat to the small end of the flare is not greater than the diameter of the outlet line; and

(3) In the case of batch pasteurizers, the outlet and the agitator are so placed as to insure that milk currents will be swept into the outlet.

4. DESIGN AND INSTALLATION OF VALVES AND CONNECTIONS:

All valves and connections shall comply with the following requirements:

a. Valves and pipeline connections shall meet the requirements of Item 10p.

b. All pipelines and fittings shall be so constructed and so located that leakage will not occur.

c. To prevent clogging, and to promote drainage, all leak-protection grooves shall be at least 5 millimeters (0.187 inch wide) and at least 2.3 millimeters (0.094 inch) deep at the center. Mating

grooves shall provide these dimensions throughout their combined length, whenever the valve is in, or approximately in, the fully closed position. All single-leak grooves, and all mating leak grooves when mated, shall extend throughout the entire depth of the seat, so as to divert leakage occurring at all points throughout the depth of the seat and so as to prevent air binding. Washers or other parts shall not obstruct leak-protector grooves.

d. A stop shall be provided on all plug-type outlet valves in order to guide the operator in closing the valve so that unpasteurized milk may not inadvertently be permitted to enter the outlet line. The stop shall be so designed that the plug will be irreversible when the plug is provided with any grooves or their equivalent, unless duplicate, diametrically opposite grooves are also provided. Stops shall be so designed that the operator cannot turn the valve beyond the stop position, either by raising the plug or by any other means.

e. Outlet valves, in addition to the requirements listed above, shall be so designed as to prevent the accumulation of unpasteurized milk in the milk passages of the valve when the valve is in any closed position.

f. All outlets from vat pasteurizers shall be equipped with close coupled leak-protector valves or be otherwise similarly protected during filling, holding and emptying periods.

g. All inlet pipelines are disconnected or otherwise similarly protected during the holding and emptying periods.

h. All leak protector valves shall be installed in the proper position to insure the function of the leak-protector grooves and the drainage of the leak detector valve.

i. All outlet valves shall be kept fully closed during filling, heating, and holding periods.

j. Close coupled vat pasteurizer outlet valve bodies and plugs shall be made of stainless steel or of other materials that have heat transfer properties at least equal to stainless steel.

5. RECORDING CHARTS

All recording thermometer charts shall comply with all the applicable requirements of Item 16p(E), p. .

ITEM 16p(B). HIGH-TEMPERATURE, SHORT-TIME, (HTST) CONTINUOUS-FLOW PASTEURIZATION

PUBLIC-HEALTH REASON

See Public-Health Reason under Item 16p and 16p(A).

ADMINISTRATIVE PROCEDURES

1. INDICATING THERMOMETER AND RECORDER/CONTROLLER INSTRUMENTS: All indicating thermometers and recorder/controller instruments and devices used in connection with the high-temperature, short-time, continuous-flow pasteurization of milk or milk products shall comply with the applicable specifications set forth in Appendix H.

2. AUTOMATIC MILK CONTROLLER: Each high-temperature, short-time, continuous-flow pasteurization system shall be equipped with an automatic milk-flow control of the diversion type, which complies with the following definition, specifications and performance requirements:

a. **"Automatic Milk-Flow Controls."**--The term "automatic milk-flow

controls" shall mean those safety devices which control the flow of milk in relation to the temperature of the milk, or heating medium and/or pressure, vacuum or other auxiliary equipment. Milk-flow controls shall not be considered as part of the temperature control equipment. Milk-flow controls shall be of the flow-diversion type which automatically cause the diversion of the milk in response to a sub-legal pasteurization temperature. At sublegal temperatures, flow-diversion devices return the milk to the raw milk side of the heating system continuously until legal pasteurization temperatures are obtained, at which time, the device restores forward flow through the pasteurizer.

b. Flow-Diversion Devices:

All flow-diversion devices used in continuous pasteurizers shall comply with the following or equally satisfactory specifications:

(1) Forward flow of sub-temperature milk, due to the omission or looseness of the connecting clip, shall be prevented by making the valve and its actuating mechanism integral; or, where there is a connecting device, by making it impossible to assemble the valve and its actuating mechanism, except in such manner that it will function properly; or where there is a connecting device which may be omitted or shaken loose by providing for pushing instead of pulling, the valve to the diverted position; or by providing that the pump will shut down when the milk is below the pasteurization temperature and the valve is not in the fully-diverted position; or by any other equally satisfactory means.

(2) When a packing gland is used to prevent leakage around the actuating stem, it shall be impossible to tighten the stem packing nut to such an extent as to prevent the valve from assuming the fully-diverted position.

(3) A leak escape shall be installed on the forward-flow side of the valve seat. However, when back pressure is exerted on the forward-flow side of the valve seat, while the milk-flow is being diverted, the leak escape should lie between two valve seats or between two portions of the same seat, one upstream and the other downstream from the leak escape. The leak escape shall be designed and installed to discharge all leakage to the outside, or to the constant-level tank through a line separate from the diversion line. *Provided*, that when leakage is discharged to the constant-level tank, a sight glass shall be installed in the leak escape line to provide a visual means of leak detection.

(4) The closure of the forward-flow seat shall be sufficiently tight so that leakage past it will not exceed the capacity of the leak escape device, as evidenced when the forward-flow line is disconnected; and, in order that proper seating may not be disturbed, the length of the connecting rod shall not be adjustable by the user.

(5) The flow-diversion device shall be so designed and installed that failure of the primary motivating power shall automatically divert the flow of milk.

(6) The flow-diversion device shall be located downstream from the holder. The flow-control sensor shall be located in the milk line not more than 46 centimeters (18 inches) upstream from the flow-control device.

(7) In the case of higher-heat, shorter-time (HHST) pasteurizing systems utilizing the temperatures of 89°C (191°F) and above and holding times of 1 second or less, the flow-diversion device may be located downstream from the regenerator and/or cooler section. *Provided*, that when the flow-diversion device is located downstream from the regenerator and/or cooler section, the flow-diversion device shall be automatically prevented from

assuming the forward-flow position until all product-contact surfaces between the holding tube and flow-diversion device have been held at or above the required pasteurization temperature continuously and simultaneously for at least the required pasteurization time as defined in Definition V of this *Ordinance*.

(8) The pipeline from the diversion port of the flow-diversion device shall be self-draining and shall be free of restrictions or valves, unless such restrictions are noticeable and valves are so designed that stoppage of the diversion line cannot occur.

(9) When it is used, the pipeline from the leak detector port of the flow-diversion device shall be self-draining and shall be free of restrictions or valves.

(10) The flow-diversion device shall be interwired, via micro-switches to the timing pump or timing system, to insure that flow occurs only when the valve(s) are in the fully divert position at below cut-in temperature. A one second maximum "off" time delay is allowable to maintain the flow-promoting device in the "on" position through the travel time of the valve(s).

(11) If the area between the divert and detect valve seats is not self draining when the flow-diversion device is in the diverted position, a delay of at least one second and not more than five seconds is required between the movement of the divert and detect valves when the flow-diversion device assumes the forward flow position. Except that: the delay may be longer than five seconds if; the timing system is magnetic flow meter based; or if the holding time in diverted flow through an unrestricted divert valve line is longer than the required pasteurization time as specified in Definition V of this *Ordinance*; and except that, no time delay is required in pasteurization systems in which the flow-

diversion device is located down stream from the pasteurized regenerator and in which all forward flow product-contact surfaces of the flow-diversion device are sanitized (or sterilized) during the normal startup process.

c. Milk-Flow Controller Instrumentation: The following requirements shall be met with respect to the instrumentation of the milk-flow controller:

(1) The thermal limit controller shall be set and sealed so that forward flow of product cannot start unless the temperature at the controller sensor is above the required pasteurization temperature as defined in Definition V of this *Ordinance* for the milk or milk product and the process used, nor continue during descending temperatures when the temperature is below the required pasteurization temperature. The seal shall be applied by the regulatory agency after testing, and shall not be removed without immediately notifying the regulatory agency. The system shall be so designed that no milk can be bypassed around the controller sensor which shall not be removed from its proper position during the pasteurization process. The cut-in and cut-out milk temperatures, as shown by the indicating thermometer, shall be determined at the beginning of each day's operation and entered upon the recorder chart daily by the plant operator.

(2) In the case of HHST pasteurization systems, utilizing the temperatures of 89°C (191°F) and above, and holding times of 1 second or less, with the flow-diversion device located downstream from the regenerator and/or cooler section, additional temperature controllers and timers shall be inter-wired with the thermal limit controller, and the control system shall be set and sealed so that forward flow of product cannot start until all product-contact surfaces between the holding tube and flow-diversion device have been held at or above

the required pasteurization temperature, continuously and simultaneously for at least the required pasteurization time as defined in Definition V of this *Ordinance*. The control system shall also be set and sealed so that forward flow cannot continue when the temperature of the product in the holding tube is below the required pasteurization temperature. The seal shall be applied by the regulatory agency after the equipment has been tested, and shall not be removed without immediately notifying the regulatory agency. The system shall be so designed that no product can be bypassed around the control sensors, which shall not be removed from their proper position during the pasteurization process. For these HHST systems, daily measurement by the operator of the cut-in and cut-out temperatures is not required.

(3) Manual switches for the control of pumps, homogenizers or other devices which produce flow through the holder, shall be wired so that the circuit is completed only when the milk is above the required pasteurization temperature as defined in Definition V of this *Ordinance* for the milk or milk product and the process used, or when the diversion device is in the fully-diverted position.

d. Holding Tube:

(1) Holders shall be designed to provide for the holding of every particle of milk or milk product for at least the time required in Definition V of this *Ordinance* for the milk or milk product and the process used.

(2) The holder shall be so designed that the simultaneous temperature difference between the hottest and coldest milk, in any cross section of flow, at any time during the holding period, will not be greater than 0.5°C (1°F). This requirement may be assumed to have been satisfied, without testing, in tubular holders of 17.8 centimeters (7 inches) or smaller diameter

which are free of any fittings through which the milk may not be thoroughly swept.

(3) No device shall be permitted for short circuiting a portion of the holder to compensate for changes in rate of milkflow. Holding tubes shall be installed so that sections of pipe cannot be left out, resulting in a shortened holding time.

(4) The holding tube shall be arranged to have a continuously upward slope in the direction of flow of not less than 2.1 centimeters per meter (0.25 inch per foot).

(5) Supports for tubes shall be provided to maintain all parts of the holding tubes in a fixed position, free from any lateral or vertical movement.

(6) The holder shall be so designed that no portion between the inlet and the flow-control temperature sensor is heated.

(7) The holding time for the HHST processes must be determined from the pumping rate rather than by the salt conductivity test, because of the short holding tube. The holding tube length must be such that the fastest flowing particle, of any product, will not traverse the holding tube in less than the required holding time. Since laminar flow (the fastest flowing particle travels twice as fast as the average flowing particle) can occur in the holding tube during pasteurization of high-viscosity products, holding tube lengths are calculated as twice the length required to hold the average flow for the time standard.

(8) With the direct steam heating processes, the holding time is reduced because the product volume increases as the steam condenses to water during heating in the injector. This surplus water is evaporated as the pasteurized product is cooled in the vacuum chamber. For example, with a 66°C (120°F) increase by steam injection, which is probably the maximum temperature rise that will be used, a volume increase of 12 percent will occur

in the holding tube. The measurement of the average flow rate, at the discharge of the pasteurizer, does not reflect this volume increase in the holding tube. However, this volume increase, i.e., holding time decrease, must be considered in the calculations.

(9) The pressure limit indicator/pressure switch must be interwired so that the flow-diversion device will move to the divert position if the product pressure falls below a prescribed value. For operating temperatures between 89°C (191°F) and 100°C (212°F) the instrument must be set at 69 kPa (10 pounds per square inch) (psi). For units which have operating temperatures above 100°C (212°F) the instrument must be set at a pressure 69 kPa (10 psi) above the boiling pressure of the product, at its maximum temperature in the holding tube. If this pressure is too low, the resultant vaporization in the holding tube will substantially reduce residence times.

(10) With the steam injection process, a differential pressure limit indicator across the injector is needed to ensure adequate isolation of the injection chamber. The instrument must have a differential pressure switch so that the flow-diversion device will move to the divert position if the pressure drop across the injector falls below 69 kPa (10 psi).

e. Indicating and Recording Thermometers:

(1) An indicating thermometer shall be located as near as practicable to the temperature sensor of the recorder/controller, but may be located a short distance upstream from the latter where milk between the two thermometers does not differ significantly in temperature.

(2) The temperature shown by the recorder/controller shall be checked daily by the plant operator against the temperature shown by the indicating thermometer. Readings shall be recorded on the chart. The recorder/controller shall be

adjusted to read no higher than the indicating thermometer.

(3) The recorder/controller charts shall comply with the applicable provisions of Item 16p(E).

f. Flow-Promoting Devices:

(1) The pump, or pumps and other equipment which may produce flow through the holder shall be located upstream from the holder, provided that pumps and other flow-promoting devices may be located downstream from the holder, if means are provided to eliminate negative pressure between the holder and the inlet to such equipment. When vacuum equipment is located downstream from the holder, an effective vacuum breaker, plus an automatic means of preventing a negative pressure in the line between the flow-diversion device and the vacuum chamber, shall be acceptable.

(2) The speed of pumps or other flow-promoting devices, governing the rate of flow through the holder, shall be so controlled as to insure the holding of every particle of milk for at least the time required as defined in Definition V of this *Ordinance* for the milk or milk product and the process used. In all cases, the motor shall be connected to the metering pump by means of a common drive shaft, or by means of gears, pulleys, or a variable-speed drive, with the gear box, the pulley box or the setting of the variable speed protected in such a manner that the holding time cannot be shortened without detection by the regulatory agency. This shall be accomplished by the application of a suitable seal(s) after being tested by the regulatory agency and such seal shall not be broken without immediately notifying the regulatory agency. This provision shall apply to all homogenizers used as timing pumps. Variable speed drives, used in connection with the metering pump, shall be so constructed that wearing or stretching of the belt results in a

slowdown, rather than a speedup, of the pump.

The metering or timing pump shall be of the positive displacement type or shall comply with the specifications for magnetic flow meter systems as outlined in Appendix H. Timing pumps and homogenizers, when used as a timing pump, shall not have bypass lines connected from their outlet pipelines to their inlet pipelines during processing if an additional flow-promoting or vacuum producing device is located within the system. When a homogenizer is used in conjunction with a timing pump it shall be either:

(i) Of larger capacity than the timing pump. In which case an unrestricted, open, recirculation line shall be used to connect the outlet pipeline from the homogenizer to its inlet line. The recirculation line must be of at least the same or larger diameter than the inlet pipeline feeding product to the homogenizer. A check valve, allowing flow from the outlet line to the inlet line, may be used in the recirculating line provided it is of the type which provides a cross-sectional area at least as large as the recirculating line.

(ii) Of smaller capacity than the timing pump. In which case a relief line and valve shall be used. Such relief line shall be located after the timing pump and before the inlet to the homogenizer and shall return product to the balance tank or to the outlet of the balance tank, upstream of any booster pump or other flow-promoting device.

For those systems which do not homogenize all products and wish to utilize a by-pass line to by-pass the homogenizer while processing such product; the by-pass line must be connected with valves which are so designed that both lines cannot be open at the same time. This may be accomplished with 3-way plug valves with properly designed and operating pins or

other automatic, fail-safe valves which accomplish the same objective.

(3) The holding time shall be taken to mean the flow time of the fastest particle of milk, at or above the required pasteurization temperature as defined in Definition V of this *Ordinance* for the milk or milk product and the process used, throughout the holder section; i.e., that portion of the system that is outside of the influence of the heating medium, and slopes continuously upward in the downstream direction and is located upstream from the flow-diversion device. Tests for the holding time shall be made when all equipment and devices are operated and adjusted to provide for maximum flow. When a homogenizer is located upstream from the holder, the holding time shall be determined with the homogenizer in operation with no pressure on the homogenizer valves.

For those systems which do not homogenize all products and utilize by-pass lines as outlined in (i) above, the holding time shall be tested in both flow patterns and the fastest time used. The holding time shall be tested during both forward and diverted flow. If it is necessary to lengthen the holding time during diverted flow, an identifiable restriction may be placed in the vertical portion of the diversion pipeline. When vacuum equipment is located downstream from the holder, the holding time shall be tested with the metering pump operating at maximum flow and the vacuum equipment adjusted to provide for the maximum vacuum.

The holding time shall be tested in both forward and diverted flow by the regulatory agency initially; semiannually thereafter; after any alteration or replacement that may affect the holding time; and whenever the seal of the speed setting has been broken.

g. Heating by Direct Addition of Steam: Steam injection is an inherently un-

stable process; accordingly, when steam is injected into a fluid, condensation of the steam may not be completed inside the injector unless the proper design criteria are used. Lack of complete condensation inside the injector would cause temperature variations in the holding tube that could lead to some product particles being processed below pasteurization temperature. When culinary steam is introduced directly into milk or milk products, as the means of terminal heating to achieve pasteurization temperature, the steam injector shall be designed, installed and operated to comply with the following or equally satisfactory specifications:

(1) The product and steam flows must be isolated from pressure fluctuations inside the injection chamber. One method of isolation is to insert supplementary orifices on the product inlet and the heated product outlet of each injector. The two supplementary orifices must be sized for at least a 69 kPa (10 psi) product pressure drop across the injector during a simulation of normal operations. Excessive vibrations, pressure fluctuations or erratic noise levels indicate an unstable steam injection system and a need to check the isolation of the injection chamber.

(2) The process should be as free as possible of noncondensable gases that may evolve from the product or be carried in the steam supply. Any two-phase flow caused by the noncondensable gases would displace the product in the holding tube, resulting in reduced residence times. In addition, these gases in the steam supply may also markedly alter the condensation mechanism at the point of injection. Accordingly, the steam boiler shall be supplied with a de-aerator. The de-aerator will aid in keeping the product in the holding tube as free as possible of noncondensable gases.

h. Prevention of Product Adulteration With Added Water:

(1) When culinary steam is introduced directly into the milk or milk product downstream from the flow-diversion device, means shall be provided to preclude the addition of steam to the product, unless the flow-diversion device is in the forward-flow position. This provision may be satisfied by the use of an automatic steam control valve with a temperature sensor located downstream from the steam inlet, or by the use of an automatic solenoid valve installed in the steam line and so wired through the flow-diversion device controls, so that steam cannot flow unless the flow-diversion device is in the forward-flow position.

(2) When culinary steam is introduced directly into the milk or milk product, automatic means (e.g., stand-alone and/or PLC-based ratio control system) shall be provided to maintain a proper temperature differential between incoming and outgoing milk to preclude dilution with water.

(3) Where a water feed line is connected to a vacuum condenser and the vacuum condenser is not separated from the vacuum chamber by a physical barrier, means shall be provided to preclude the backup and overflow of water from the vacuum condenser to the vacuum chamber. This provision may be satisfied by the use of a safety shutoff valve, located on the water feed line to the vacuum condenser, which is automatically actuated by a control which will shut off the in-flowing water, if for example, the condensate pump stops and the water level rises above a predetermined point in the vacuum condenser. This valve may be actuated by water, air or electricity and shall be so designed that failure of the primary motivating power will automatically stop the flow of water into the vacuum condenser.

ITEM 16p(C). ASEPTIC PROCESSING SYSTEMS

PUBLIC HEALTH REASON

Aseptically processed milk and milk products are being packaged in hermetically sealed containers and stored for long periods of time under nonrefrigerated conditions. These conditions are favorable to the growth of many types of bacteria. (Pathogenic, toxin producing and spoilage organisms.) Because of this, every precaution must be taken to ensure that all viable organisms and their spores are destroyed by the chosen heat process, for the particular milk or milk product, and that the subsequent handling, packaging and storage processes do not provide an opportunity for recontamination of the product. The selected process must conform to the acceptable requirements for low acid canned foods.

ADMINISTRATIVE PROCEDURES

Aseptic Processing Systems

The aseptic processing portion of this Item is deemed to be satisfied when the design and operation of aseptic processing systems comply with the applicable specifications and operational procedures of subitems (C), (D) and (E) as follows:

Provided, that nothing shall be construed as barring any other aseptic processing system which have been recognized by the Food and Drug Administration to be equally effective and which is approved by the regulatory agency.

1. INDICATING THERMOMETERS AND RECORDER-CONTROLLER INSTRUMENTS: All indicating thermometers, recorder/controller instruments and devices, used in connection with aseptic processing systems, used for the aseptic processing of milk or milk products shall comply with the applicable specifications set forth in Appendix H.

2. ASEPTIC PROCESSING EQUIPMENT:

a. Temperature Indicating Device-- Each aseptic processing system shall be equipped with at least one mercury-in-glass thermometer or an equivalent temperature-indicating device.

b. Temperature Recorder-Controller-- An accurate temperature recorder/controller shall be installed in the product at the holding-tube outlet and before the inlet to the cooler or regenerator. The following requirements shall be met with respect to the instrumentation of the temperature recorder/controller.

(1) The temperature recorder/controller shall be set and sealed so that during product processing the forward flow of product cannot start unless the temperature at the controller sensor is above the required temperature for the product and the process used, nor continue during descending temperatures when the temperature is below the required temperature.

The seal shall be applied by the regulatory agency after testing and shall not be removed without immediately notifying the regulatory agency. The system shall be so designed that no product can be bypassed around the controller sensor which shall not be removed from its proper position during the processing of aseptic milk and milk products.

(2) Additional temperature controllers and timers shall be interwired

with the thermal limit controller, and the control system shall be set and sealed so that forward flow of product cannot start until all product-contact surfaces between the holding tube and flow-diversion device have been held at or above the required sterilization temperature, continuously and simultaneously for at least the required sterilization time. The control system shall also be set and sealed so that forward flow cannot continue when the temperature of the product in the holding tube is below the required temperature. The seal shall be applied by the regulatory agency after being tested and shall not be removed without immediately notifying the regulatory agency. The system shall be so designed that no product can be bypassed around the control sensors, which shall not be removed from their proper position during the processing of aseptic milk and milk products.

(3) Manual switches for the control of pumps, homogenizers or other devices which produce flow through the holder, shall be wired so that the circuit is completed only when the milk is above the required temperature for the product and the process used, or when the diversion device is in the fully-diverted position.

c. Metering Pump:

(1) A metering pump shall be located upstream from the holding tube and shall be operated to maintain the required rate of product flow. The motor shall be connected to the metering pump by means of a common drive shaft, or by means of gears, pulleys or a variable-speed drive, with the gear box, the pulley box or the setting of the variable speed protected in such a manner that the hold time cannot be shortened without detection by the regulatory agency. This shall be accomplished by the application of a suitable seal(s) after being tested by the regulatory agency and such seal shall not be broken without

immediately notifying the regulatory agency. This provision shall apply to all homogenizers used as timing pumps. Variable speed drives, used in connection with the metering pump, shall be so constructed that wearing or stretching of the belt results in a slowdown, rather than a speedup, of the pump. The metering or timing pump shall be of the positive displacement type or shall comply with the specifications for magnetic flow meter systems.

(2) The holding time shall be taken to mean the flow time of the fastest particle of product throughout the holder section; i.e., that portion of the system that is outside of the influence of the heating medium; and slopes continuously upward in the downstream direction; and is located upstream from the flow-diversion device. Tests for holding time shall be made when all equipment and devices are operated and adjusted to provide for maximum flow. When a homogenizer is located upstream from the holder, the holding time shall be determined with the homogenizer in operation with no pressure on the homogenizer valves. Where bypass lines are provided, either upstream or downstream from the metering pump, the holding time shall be tested with both the regular and bypass line open, unless the bypass valve is so designed that both lines cannot be open at the same time. When vacuum equipment is located downstream from the holder, the holding time shall be tested with the metering pump operating at maximum flow and the vacuum equipment adjusted to provide for maximum vacuum. The holding time shall be tested by the regulatory agency initially; semiannually thereafter; after any alteration or replacement that may affect the holding time; and whenever the seal of the speed setting has been broken.

d. Product Holding Tube:

(1) The product holding tube shall be designed to give continuous holding of every particle of product for at least the minimum holding time specified in the scheduled process. The holding tube shall be designed, so that no portion of the tube between the product inlet and the product outlet can be heated and it must be sloped upward at least 2.1 centimeters per meter (0.25 inch) per foot. Supports for tubes shall be provided to maintain all parts of the holding tubes in a fixed position, free from any lateral or vertical movement.

(2) No device shall be permitted for short circuiting a portion of the holder to compensate for changes in rate of production flow. Holding tubes shall be installed so that sections of pipe cannot be left out, resulting in a shortened holding time. The holding time for the processes must be determined from the pumping rate, rather than by the salt conductivity test.

(3) The holding tube length must be such that the fastest flowing particle of any product will not traverse the holding tube in less than the required holding time.

NOTE: Since laminar flow (the fastest flowing particle travels twice as fast as the average flowing particle) can occur in the holding tube during aseptic processing of high-viscosity products, holding tube lengths are calculated as twice the length required to hold the average flow for the time standard. With the steam injection process, the holding time is reduced because the product volume increases as the steam condenses to water during heating in the injector. This surplus water is evaporated as the aseptically processed product is cooled in the vacuum chamber. For example, with a 66°C (120°F) increase by steam injection, which is probably the maximum temperature rise that will be used, a volume increase of 12 percent will occur in the holding tube. The measurement of the average flow rate at

the discharge of the aseptic processor does not reflect this volume increase in the holding tube. However, this volume increase, i.e., holding time decrease, must be considered in the calculations.

(4) An aseptic processing system which can operate with product in forward flow mode, with less than 518 kPa (75psig) pressure in the holding tube shall be equipped with a pressure limit indicator/pressure switch in the holding tube to assure that the heated product remains in the liquid phase. In systems which do not have a vacuum chamber between the holding tube and the aseptic product side of the regenerator, this can be established by verifying that the aseptic processing equipment cannot operate in forward flow with less than 518 kPa (75psig) pressure on the aseptically processed side of the regenerator (see PMO test 9). The pressure limit indicator/pressure switch must be interwired so that the flow-diversion device, product divert system, product divert valve or other acceptable control system will move to the divert position, if the product pressure falls below a prescribed value. The instrument must be set at a pressure 69 kPa (10 psi) above the boiling pressure of the product at its maximum temperature in the holding tube. If this pressure is too low, the resultant vaporization in the holding tube will substantially reduce residence times.

(5) With the steam injection process, a differential pressure limit indicator, across the injector, is needed to ensure adequate isolation of the injection chamber. The instrument must have a differential pressure switch so that the flow-diversion device will move to the divert position if the pressure drop across the injector falls below 69 kPa (10 psi).

e. Heating by Direct Addition of Steam: Steam injection is an inherently unstable process; accordingly, when steam is injected into a fluid, condensation of the

steam may not be completed inside the injector unless the proper design criteria are used. Lack of complete condensation inside the injector would cause temperature variations in the holding tube, that could lead to some product particles being processed below filed process temperature. When culinary steam is introduced directly into milk or milk products, as the means of terminal heating to achieve aseptic processing temperature, the steam injector shall be designed, installed and operated to comply with the following or equally satisfactory specifications:

(1) The product and steam flows must be isolated from pressure fluctuations inside the injection chamber. One method of isolation is to insert supplementary orifices on the product inlet and the heated product outlet of each injector. The two supplementary orifices must be sized for at least a 69 kPa (10 psi) product pressure drop across the injector during a simulation of normal operations. Excessive vibrations, pressure fluctuations or erratic noise levels indicate an unstable steam injection system and a need to check the isolation of the injection chamber.

(2) The process should be as free as possible of noncondensable gases that may evolve from the product or be carried in the steam supply. Any two-phase flow, caused by the noncondensable gases, would displace the product in the holding tube, resulting in reduced residence times. In addition, these gases in the steam supply may also markedly alter the condensation mechanism at the point of injection. Accordingly, the steam boiler shall be supplied with a de-aerator. The de-aerator will aid in keeping the product in the holding tube as free as possible of noncondensable gases.

f. Prevention of Product Adulteration With Added Water:

(1) When culinary steam is introduced directly into the milk or milk

product, automatic means (e.g., stand-alone and/or PLC-based ratio control system) shall be provided to maintain a proper temperature differential between incoming and outgoing milk to preclude dilution with water.

(2) Where a water feed line is connected to a vacuum condenser and the vacuum condenser is not separated from the vacuum chamber by a physical barrier, means shall be provided to preclude the back-up and overflow of water from the vacuum condenser to the vacuum chamber. This provision may be satisfied by the use of a safety shutoff valve, located on the water feed line to the vacuum condenser, which is automatically actuated by a control, which will shut off the in-flowing water, if for example, the condensate pump stops and the water level rises above a predetermined point in the vacuum condenser. This valve may be actuated by water, air or electricity and shall be so designed that failure of the primary motivating power will automatically stop the flow of water into the vacuum condenser.

g. **Flow-Diversion Device:** All flow-diversion devices used in continuous aseptic process systems shall comply with 16p(B).2.b. or equally satisfactory specifications.

ITEM 16p(D). PASTEURIZERS AND ASEPTIC PROCESSING SYSTEMS EMPLOYING REGENERATIVE HEATING

PUBLIC HEALTH REASON

To prevent contamination of the pasteurized milk in regenerators, the raw milk must always be under less pressure than the pasteurized milk or the heat-transfer medium. In the case of milk-to-milk regenerators, this requirement is necessary to prevent contamination of the pasteurized product by the raw milk if flaws should develop in the metal or in the joints separating the two kinds of milk.

ADMINISTRATIVE PROCEDURES

Milk-to-Milk Regenerative Heating

Pasteurizers and aseptic processing systems employing milk-to-milk regenerative heating with both sides closed to the atmosphere shall comply with the following or equally satisfactory specifications:

1. Regenerators shall be constructed, installed and operated so that pasteurized or aseptic product in the regenerator will automatically be under greater pressure than raw milk in the regenerator at all times.

2. The pasteurized or aseptic product, between its outlet from the regenerator and the nearest point downstream open to the atmosphere, shall rise to a vertical elevation of 30.48 centimeter (12 inches) above the highest raw milk level, downstream from the constant-level tank, and shall be open to the atmosphere at this or a higher elevation.

3. The overflow of the top rim of the constant level raw milk tank shall always

be lower than the lowest milk level in the regenerator.

4. No pump or flow-promoting device which can affect the proper pressure relationships within the regenerator shall be located between the pasteurized or aseptic product outlet from the regenerator and the nearest downstream point open to the atmosphere.

5. No pump shall be located between the raw milk inlet to the regenerator and the raw milk supply tank, unless it is designed and installed to operate only when milk is flowing through the pasteurized or aseptic product side of the regenerator and when the pressure of the pasteurized or aseptic product is higher than the maximum pressure produced by the pump. This may be accomplished by wiring the booster pump so that it cannot operate unless:

a. The metering pump is in operation;

b. The flow-diversion device is in forward-flow position; and

c. The pasteurized or aseptic product pressure exceeds, by at least 6.9 kPa (1 psi), the maximum pressure developed by the booster pump. Pressure gauges shall be installed at the raw milk inlet to the regenerator and the pasteurized or aseptic product outlet of the regenerator or the outlet of the cooler. The accuracy of these required pressure gauges shall be checked, by the regulatory agency, on installation; quarterly thereafter; and following repair or adjustment.

6. The motor, casing and impeller of the booster pump shall be identified, and such records maintained as directed by the regulatory agency. All electric wiring interconnections should be in permanent conduit (except that rubber covered cable may be used for final connections), with no electrical connections to defeat the purpose of any provisions of this *Ordinance*.

7. All raw milk in the regenerator will drain freely back into the constant-level raw milk tank when the raw milk pump(s) are shut down and the raw milk outlet from the regenerator is disconnected.

8. When vacuum equipment is located downstream from the flow-diversion device, means shall be provided to prevent the lowering of the pasteurized or aseptic product level in the regenerator during periods of diverted flow or shutdown. An effective vacuum breaker, plus an automatic means of preventing a negative pressure, shall be installed in the line between the vacuum chamber and the pasteurized or aseptic product inlet to the regenerator.

9. In the case of HHST pasteurization systems utilizing the temperatures of 89°C (191°F) and above and holding times of 1 second or less, with the flow-diversion device located downstream from the regenerator and/or cooler section, the requirement that the pasteurized product from the outlet of the regenerator or cooler shall rise to a vertical elevation of 30.5 centimeters (12 inches) above the highest raw product level downstream from the constant-level tank and shall be open to the atmosphere at this or a higher elevation, may be eliminated. *Provided*, that a differential pressure controller is used to monitor the highest pressure in the raw product side of the regenerator and the lowest pressure in the pasteurized side of the regenerator, and the controller is interlocked with the flow-diversion device and is set and sealed so that whenever improper pressures occur in the regenerator, forward flow of product is automatically prevented and will not start again until all product-contact surfaces between the holding tube and flow-diversion device have been held at or above the required pasteurization temperature, continuously and simultaneously for at least the required pasteurization time as defined in Definition V of this *Ordinance*.

In the case of aseptic processing systems used for producing aseptic milk and milk products, there shall be an accurate differential pressure recorder-controller installed on the regenerator. The scale divisions shall not exceed 13.8 kPa (2 pounds per square inch) on the working scale of not more than 138 kPa (20 pounds per square inch) per 25.4 millimeter (1 inch). The controller shall be tested for accuracy against a known accurate standard pressure indicator upon installation; at least once every 3 months of operation thereafter; or more frequently if necessary, to ensure its accuracy. One pressure sensor shall be installed at the aseptic product regenerator outlet and the other pressure sensor shall be installed at the raw product regenerator inlet.

10. When culinary steam is introduced directly into milk or milk products, as the means of terminal heating to achieve pasteurization or aseptic processing temperature, and vacuum equipment is located downstream from the holding tube, the requirement that a vacuum breaker be installed at the inlet to the pasteurized or aseptic side of the regenerator may be eliminated. *Provided*, that the differential pressure controller is installed and wired to control the flow-diversion device as described in paragraph 9 of this section.

11. When the differential pressure controller is installed and wired to control the flow-diversion device as described in paragraph 9 of this section, the raw product booster pump may be permitted to run at all times. *Provided*, that the metering pump is in operation.

Milk-to-Water-to Milk Regenerative Heating

Milk-to-water-to-milk regenerators shall comply with the following or equally satisfactory specifications:

Milk-to-water-to-milk regenerators shall be constructed, installed and operated such that the pasteurized or aseptic product in the regenerator will be under greater pressure than the heat-transfer-medium in the pasteurized or aseptic product side of the regenerator.

1. A differential pressure controller shall be used to monitor pressures of the pasteurized product and the heat-transfer medium.

2. In the case of aseptic processing systems, a differential pressure-recorder shall be used to monitor pressures of the aseptic product and the heat transfer medium.

3. In either case, one pressure sensor shall be installed at the pasteurized or aseptic product outlet of the regenerator and the other pressure sensor shall be installed at the heat-transfer-medium inlet of the pasteurized or aseptic product side of the regenerator. This controller or recorder-controller shall divert the flow-diversion device whenever the lowest pressure of pasteurized or aseptic product in the regenerator fails to exceed the highest pressure of heat-transfer-medium in the pasteurized or aseptic product side of the regenerator by at least 6.9 kPa (1 psi). Forward flow of product shall be automatically prevented until all product-contact surfaces between the holding tube and the flow-diversion device have been held at or above the required pasteurization or sterilization temperature continuously and simultaneously for at least the pasteurization or sterilization time.

4. The heat-transfer-medium pump shall be wired so that it cannot operate unless the metering pump is in operation.

NOTE: See Appendix H for further discussion concerning methods of achieving the required pressure relationships within the regenerator.

**ITEM 16p(E). PASTEURIZATION AND
ASEPTIC PROCESSING RECORDS,
EQUIPMENT TESTS AND
EXAMINATIONS**

**1. PASTEURIZATION AND
ASEPTIC PROCESSING RECORDS:**

All temperature and flow rate pasteurization recording charts or alternative records acceptable to FDA in place of charts shall be preserved for a period of 3 months. *Provided*, that all records and recording charts for aseptic milk and milk product systems shall be retained for a period of 3 years. The use of such charts shall not exceed the time limit for which they are designed. Overlapping of recorded data shall be a violation of this item. The following information shall be entered on the charts or other records acceptable to FDA in place of charts as applicable:

a. Batch Pasteurizers:

- (1) Date.
- (2) Number or location of recorder when more than one is used.
- (3) A continuous record of the product temperature.
- (4) Extent of holding period, including filling and emptying times when required.
- (5) Reading of airspace thermometer, at the start of the holding period and at the end of the holding period, at a given time or reference point as indicated on the chart.
- (6) Reading of indicating thermometer, at the start of the holding period, at a given time or reference point as indicated on the chart.
- (7) Quarterly, the initials of the regulatory agency opposite the required readings of the indicating thermometer and airspace thermometer.
- (8) Quarterly, the time accuracy of the recorder, as determined by the regulatory agency.

(9) Amount and name of pasteurized milk or milk product represented by each batch or run on the chart.

(10) Record of unusual occurrences.

(11) Signature or initials of operator.

(12) Name of milk plant.

b. High-Temperature, Short-Time Pasteurizers, Higher Heat, Shorter Time Pasteurizers:

Recording thermometer charts shall contain all the information specified in a. above, except 4, 5 and reference to the airspace thermometer in item 7, and in addition, shall include the following:

(1) A record of the time during which the flow-diversion device is in the forward-flow position.

(2) The cut-in and cut-out milk temperatures, recorded daily by the operator, at the beginning of the run (HTST only), and initialed quarterly by the regulatory agency.

(3) Number six from above shall also be recorded immediately after a chart has been changed.

NOTE: The recorded temperature shown on the controller chart shall be used to determine that the required temperature for milk products containing higher fat and/or sweeteners has been achieved.

c. Continuous Flow Pasteurizers or Aseptic Processing Equipment with Meter Based Timing Systems:

Flow rate recording charts shall be capable of continuously recording flow at the flow alarm set point and at least 19 liters (5 gallons) per minute higher than the high flow alarm setting. Flow rate recording charts shall contain all the information specified in a. above, except 3, 4, 5, 6, and 7 and in addition shall include the following:

(1) A record of the time during which the flow-diversion device is in the forward-flow position.

(2) A continuous record of the flow rate.

d. **Aseptic Processing Systems:** Recording charts shall contain all the information specified in a. above, except 4, 5 and reference to the airspace thermometer in item 6 and 7. In addition these records shall include c. above if applicable and the following:

(1) A continuous record of the time during which the flow-diversion device, valve or system is in the forward-flow position.

(2) A continuous record of applicable regenerator pressures.

(3) Not later than 1 working day after the actual process, and before shipment or release for distribution, a representative of plant management, who is qualified by suitable training or experience, shall review all processing and production records for completeness and to ensure that the product received the schedule process. The records, including the recording thermometer chart(s), shall be signed or initialed and dated by the reviewer.

(4) Number six from above shall also be recorded immediately after a chart has been changed.

2. EQUIPMENT TESTS AND EXAMINATIONS: The regulatory agency shall perform the indicated tests on the following instruments and devices initially on installation; and at least once each 3 months and the remaining days of the month in which the equipment tests are due and whenever any alteration or replacement is made which may affect the proper operation of the instrument or device. *Provided*, that the holding time test shall be conducted at least every 6 months and the remaining days of the month in which the equipment check is due.

On an emergency basis, pasteurization equipment may be tested and temporarily sealed by a dairy plant employee provided the following conditions are met:

a. The individual applying the seal(s) is employed in a supervisory capacity by the plant in which the seal was removed;

b. The individual has satisfactorily completed a course of instruction, acceptable to the regulatory agency, on test controls for pasteurization equipment that includes a minimum of 8 hours classroom instruction;

c. The individual has demonstrated the ability to satisfactorily conduct all pasteurization control tests, in the presence of a regulatory official, within the past year;

d. The individual is in possession of authorization from the regulatory agency to perform these tests;

e. The individual will immediately notify the regulatory agency of the time of the shutdown that would necessitate the removal of the regulatory seals. Permission to test (and seal) the equipment must be obtained for each specific incident. The individual will also notify the regulatory agency of the identity of the controls affected, the cause (if known) of the equipment failure, the repairs made and the results of testing (when completed). The individual will provide the identity and volume of products processed during the period that temporary seals were applied to the regulatory agency;

f. If regulatory tests reveal that equipment or controls are not in compliance with the provisions of this document, all products that were processed during that period will be recalled;

g. The regulatory agency or a properly trained regulatory official (commissioned by the responsible state) of each participating non-U.S. country or political subdivision thereof will remove the

temporary seals, retest the equipment and apply regulatory seals within 3 working days of notification by industry; and

h. No Grade “A” dairy products will be processed after three working days without the affected equipment being tested and sealed by the regulatory agency or a properly trained regulatory official (commissioned by the responsible state) of each participating non-US country or political subdivision thereof.

Table 4. Equipment Tests--Batch, HTST, HHST and Aseptic Processing Systems

1.	Vat, HTST, HHST, Aseptic indicating and airspace thermometers	Temperature accuracy
2.	Vat, HTST, HHST, Aseptic recording thermometer	Temperature accuracy
3.	Vat, HTST, HHST, Aseptic recording thermometer	Time accuracy
4.	Vat, HTST, HHST, Aseptic indicating and recording thermometer	Recording vs. Indicating thermometer
5.1	HTST, HHST FDD	Leakage pass FDD
5.2	HTST, HHST FDD	FDD freedom of movement
5.3	HTST, HHST FDD	Device assembly (single stem)
5.4	HTST, HHST FDD	Device assembly (dual stem)
5.5	HTST FDD	Manual diversion
5.6	HTST, HHST FDD	Response time
5.7	HTST, HHST FDD	Time delay (inspect)
5.8	HTST, HHST FDD	Time delay (CIP)
5.9	HTST FDD	Time delay (leak detect flush)
6.	Vat leak protector valve(s)	Leakage
7.	HTST indicating thermometers	Response time
8.	HTST recording thermometers	Response time
9.1	HTST pressure switches	Regenerator pressures
9.2.1	HTST, HHST, Aseptic differential pressure controllers	Calibration
9.2.2	HTST differential pressure controllers	Regenerator pressure
9.2.3	HHST and Aseptic differential pressure controllers	Regenerator pressure
9.3.1	HTST booster pump/FDD	Interwiring check
9.3.2	HTST booster pump/metering pump	Interwiring check
10.1	HTST FDD	Temperature cut-in/cut-out
10.2	HHST FDD, Aseptic divert system (indirect heat)	Temperature cut-in/cut-out
10.3	HHST FDD, Aseptic divert system (direct heat)	Temperature cut-in/cut-out
11.1	HTST holding tubes/timing pumps (except meter based)	Holding time
11.2.a	HTST holding tubes/magnetic flow meter based timing systems	Holding time
11.2.b	HTST, HHST, Aseptic magnetic flow meter based timing systems	Flow alarm
11.2.c	HTST, HHST, Aseptic magnetic flow meter based timing systems	Loss of signal/low flow
11.2.d	HTST magnetic flow meter based timing systems	Flow rate cut-in/cut-out
11.2.e	HTST magnetic flow meter based timing systems	Time delay
11.3	HHST holding tubes indirect heat	Holding time
11.4	HHST holding tubes direct injection heat	Holding time
11.5	HHST holding tubes direct infusion heat	Holding time
12.1	HHST, Aseptic systems indirect heating	Sequence logic
12.2	HHST, Aseptic systems direct heating	Sequence logic
13.	HHST, Aseptic systems	Pressure in the holding tube
14.	HHST, Aseptic systems using direct injection heating	Pressure differential across injector

ITEM 17p. COOLING OF MILK

All raw milk and milk products shall be maintained at 7°C (45°F) or less until processed. All pasteurized milk and milk products, except those to be cultured, shall be cooled immediately prior to filling or packaging, in approved equipment, to a temperature of 7°C (45°F) or less. All pasteurized milk and milk products shall be stored at a temperature of 7°C (45°F) or less. On delivery vehicles, the temperature of milk and milk products shall not exceed 7°C (45°F). Every room or tank in which milk or milk products are stored shall be equipped with an accurate thermometer. *Provided*, that aseptically processed milk and milk products to be packaged in hermetically sealed containers shall be exempt from the cooling requirements of this item.

PUBLIC-HEALTH REASON

When milk is not cooled within a reasonable time, after it is received at the pasteurization plant, its bacterial content will be materially increased. The same reasoning applies to cooling the milk and milk products after pasteurization.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. All raw milk and milk products are maintained at 7°C (45°F) or less until processed.

2. All pasteurized milk and milk products, except those to be cultured, are cooled immediately in approved equipment prior to filling and packaging to a temperature of 7°C (45°F) or less. All pasteurized milk and milk products shall be stored at a temperature of 7°C (45°F) or less. On delivery vehicles, the temperature of

milk and milk products shall not exceed (7°C) 45°F.

3. Each refrigerator room in which milk or milk products are stored, except aseptically processed milk and milk products, is equipped with an indicating thermometer which complies with the applicable specifications of Appendix H. Such thermometer shall be located in the warmest zone of the refrigerator room.

Each storage tank shall be equipped with an indicating thermometer, the sensor of which shall be located to permit the registering of the temperature of the contents when the tank contains no more than 20 percent of its calibrated capacity. Such thermometer shall comply with the applicable specifications of Appendix H.

4. All surface coolers comply with the following specifications:

a. The sections of open-surface coolers shall be so installed as to leave a gap of at least 6.4 millimeters (0.25 inch) between the header sections to permit easy cleaning.

b. Where header ends are not completely enclosed within the cooler covers, condensation or leakage from the headers shall be prevented from entering the milk or milk products by so shaping the exposed header faces, above and below all gaps, that condensation is directed away from the tubes, and by using deflectors at the bottom of the headers; or by shortening the bottom of the headers; or by shortening the bottom trough; or by some other approved method.

c. The location of supports of cooler sections shall prevent drip from entering the milk or milk products.

d. All open-surface coolers shall be provided with tight-fitting shields which protect the milk and milk products from contamination by flies, dust, drip, splash or manual contact.

5. Recirculated cold water which is used in coolers and exchangers, including those systems in which a freezing point depressant is used, is from a safe source and protected from contamination. Such water shall be tested semiannually and shall comply with the bacteriological standards of Appendix G. Samples shall be taken by the regulatory agency and examination shall be conducted in an official laboratory. Recirculated water systems, which become contaminated through repair work or otherwise, shall be properly treated and tested before being returned to use. Freezing point depressants, when used in recirculating systems, shall be nontoxic.

ITEM 18p. BOTTLING AND PACKAGING

Bottling and packaging of milk and milk products shall be done at the place of pasteurization in a sanitary manner by approved mechanical equipment.¹⁶

¹⁶ Communities and/or States desiring to regulate the sale of cottage cheese, dry curd cottage cheese and reduced fat or lowfat cottage cheese under the terms of this *Ordinance* should add the following:

"*Provided*, that cottage cheese, dry curd cottage cheese and reduced fat or lowfat cottage cheese may be transported in sealed containers in a protected, sanitary manner from one plant to another for creaming and/or packaging."

"If suitable equipment is not available for packaging dry curd cottage cheese, other methods of packaging which eliminate possible chances of contamination may be approved by the regulatory agency."

PUBLIC-HEALTH REASON

Manual bottling and packaging is very apt to result in the exposure of the milk and milk products to contamination, which would nullify the effect of pasteurization. The transfer of milk from the place of pasteurization to another plant for bottling subjects the pasteurized product to unnecessary risks of contamination.

ADMINISTRATIVE PROCEDURES¹⁷

This item is deemed to be satisfied when:

1. All milk and milk products, including concentrated milk and milk products, are bottled and packaged at the plant where final pasteurization is performed. Such bottling and packaging shall be done without undue delay following final pasteurization.

2. All bottling or packaging is done on approved mechanical equipment. The term "approved mechanical equipment" shall not be interpreted to exclude manually operated machinery, but is interpreted to exclude methods in which the bottling and capping devices are not integral in one system.

3. All pipes, connections, defoaming devices and similar

¹⁷ Communities and/or States desiring to regulate the sale of cottage cheese, dry curd cottage cheese and reduced fat or lowfat cottage cheese under the terms of this *Ordinance* should add the following to the Administrative Procedures of Item 18p:

"If cottage cheese, and dry curd cottage cheese are protected in a sanitary manner; they may be transported in sealed containers from one plant to another for creaming and/or packaging."

appurtenances shall comply with items 10p and 11p of this section. Milk and milk products from continuous defoamers are not returned directly to the filler bowl.

4. Bottling or packaging machine supply tanks and bowls have covers which are constructed to prevent any contamination from reaching the inside of the filler tank or bowl. All covers shall be in place during operation.

5. A drip deflector is installed on each filler valve. Such drip deflector shall be designed and adjusted to divert condensation away from the open container.

6. Container in-feed conveyors to automatic bottling or packaging machines have overhead shields to protect the bottles or packages from contamination. Such shields shall extend from the bottle washer discharge to the bottle feed star, or in the case of single-service packaging machines, from the forming unit discharge to the filling unit and from the filling unit to the closure unit. Overhead shields shall be required on can in-feed conveyors when the cans are fed to the filler with the covers off.

7. Container coding/dating devices are designed, installed and operated such that the coding/dating operations are performed in such a manner that open containers are not subjected to contamination. Shielding shall be properly designed and installed to preclude contamination of open containers.

8. Container fabricating materials, such as paper stock, foil, wax, plastic, etc., are handled in a sanitary manner and protected against undue exposure during the package assembly operation.

9. Bottling and packaging machine floats are designed to be adjustable without removing the cover.

10. The filler pipe of all bottling and packaging machines have an apron or other approved device, as close to the filler bowl as possible, to prevent condensation or

dripping from reaching the inside of the filler bowl.

11. Filling cylinders on packaging machines are protected from contamination by the use of overhead shields. When any lubricant is applied to the filler pistons, cylinders or other milk-contact surfaces, the lubricant shall be food-grade and applied in a sanitary manner.

12. In the case of aseptic processing systems used for producing aseptic milk and milk products, the aseptic product shall be aseptically filled into sterilized containers and hermetically sealed in conformance with the applicable requirements of 21 CFR 113.

ITEM 19p. CAPPING

Capping or closing of milk and milk product containers shall be done in a sanitary manner by approved mechanical capping and/or closing equipment. The cap or closure shall be designed and applied in such a manner that the pouring lip is protected to at least its largest diameter and, with regard to fluid product containers, removal cannot be made without detection.

PUBLIC-HEALTH REASON

Hand-capping exposes the milk to contamination. A cover extending over the pouring lip of the container protects it from contamination during subsequent handling, and prevents the sucking back into the bottle, by temperature contraction, of any contaminated liquid on the cap, including milk which has been forced out by temperature expansion and which may have become contaminated. Caps or closures that are applied in such a manner that they cannot be removed without detection help to assure the consumer that the milk and milk products have not been contaminated after packaging.

ADMINISTRATIVE PROCEDURES¹⁸

This item is deemed to be satisfied when:

1. The capping or closing of milk and milk product containers is done in a sanitary manner on approved mechanical capping/closing equipment. The term "approved mechanical capping and/or closing equipment" shall not exclude manually operated machinery. Hand-capping shall be prohibited. *Provided*, that if suitable mechanical equipment, for the capping or closing of specific container(s) of 12.8

¹⁸ Communities and/or States desiring to regulate the sale of cottage cheese, dry curd cottage cheese, and reduced fat or lowfat cottage cheese under the terms of this *Ordinance* should add the following to the indicated Administrative Procedures of Item 19p:

1. "*Provided further*, that if suitable equipment is not available for capping cottage cheese, dry curd cottage cheese and reduced fat or lowfat cottage cheese, other methods of capping which eliminate possible chances of contamination may be approved by the regulatory agency.

4. Closures for cottage cheese, dry curd cottage cheese and reduced fat or lowfat cottage cheese containers shall extend over the top edges of the container so as to protect the product from contamination during subsequent handling.

5. *Provided*, that this requirement shall not apply to cottage cheese, dry curd cottage cheese, and reduced fat or lowfat cottage cheese container closures, when such closures are supplied in a totally enclosed package, or wrapped so as to protect the closures."

liters (3 gallons) or more is not available, other methods which eliminate all possibility of contamination may be approved by the regulatory agency.

2. Bottles and packages which have been imperfectly capped or closed are emptied immediately into approved sanitary containers. Such milk or milk products shall be protected from contamination, maintained at 7°C (45°F) or less and subsequently repasteurized or discarded.

3. All caps and closures are designed and applied in such a manner that the pouring lip is protected to at least its largest diameter and, with respect to fluid product containers, removal cannot be made without detection. Single-service containers are so constructed that the product and the pouring and opening areas are protected from contamination during handling, storage and when the containers are initially opened.

4. All caps and closures are handled in a sanitary manner. The first cap from each tube, the first lap(s) from each roll of cap or cover stock and the first sheet of parchment or cover paper shall be discarded. The subsequent use of loose caps which are left in the cappers at the end of an operating period, after removal from the cap tubes, shall be a violation of this item, *provided*, that loose plastic caps and closures supplied by the manufacturer in plastic bags may be returned to storage in a protective wrap if removed from a hopper/descrambler immediately after a production run. Plastic caps and closures remaining in the chute between the hopper and the capping device shall be discarded.

**ITEM 20p. PERSONNEL--
CLEANLINESS**

Hands shall be thoroughly washed before commencing plant functions and as often as may be required to remove soil and contamination. No employee shall resume work after visiting the toilet room without thoroughly washing his hands. All persons, while engaged in the processing, pasteurization, handling, storage or transportation of milk, milk products, containers, equipment and utensils shall wear clean outer garments. All persons, while engaged in the processing of milk or milk products shall wear adequate hair coverings and shall not use tobacco.

PUBLIC-HEALTH REASON

Clean clothing and clean hands (including clean fingernails) reduce the possibility of milk, milk products, containers and equipment becoming contaminated.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. Hands are thoroughly washed before commencing plant functions and as often as may be required to remove soil and contamination.
2. Each employee washes his hands following a visit to the toilet room and prior to resuming work.
3. All persons while engaged in the processing, pasteurization, handling, storage or transportation of milk, milk products, containers, equipment and utensils wear clean outer garments.
4. The use of tobacco products is prohibited in all rooms in which milk or milk products are processed, handled or stored, or in which milk containers,

equipment and utensils are washed. These rooms shall include, but are not limited, to the receiving, processing, packaging, product storage (cooling and dry storage ingredients), single-service article storage and container/utensil wash up areas. Adequate head coverings are worn by any person engaged in the processing of milk or milk products.

ITEM 21p. VEHICLES

All vehicles used for the transportation of pasteurized milk and milk products shall be constructed and operated so that the milk and milk products are maintained at 7°C (45°F) or less and are protected from contamination.

PUBLIC-HEALTH REASON

Milk and milk products, as well as empty containers, should be protected against contamination at all times.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. All vehicles are kept clean.
2. Material which is capable of contaminating milk or milk products is not transported with milk or milk products.
3. Vehicles have fully enclosed bodies with well-fitted, solid doors.

ITEM 22p. SURROUNDINGS

Milk plant surroundings shall be kept neat, clean and free from conditions which might attract or harbor flies, other insects and rodents or which otherwise constitute a nuisance.

PUBLIC-HEALTH REASON

The surroundings of a dairy plant should be kept neat and clean to prevent attracting rodents, flies and other insects, which may contaminate the milk or milk products. Insecticides and rodenticides, not approved for use in dairy plants, or approved insecticides and rodenticides, not used in accordance with label recommendations, may contaminate the milk or milk product processed by the dairy plant.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. There is no accumulation of trash, garbage or similar waste in areas adjacent to the milk plant. Waste material stored in suitable covered containers shall be considered in compliance.

2. Driveways, lanes and areas serving milk plant vehicular traffic are graded, drained and free from pools of standing water.

3. Outdoor areas for milk tank truck unloading are constructed of smooth concrete or equally impervious material, properly sloped to drain and equipped with trapped drains of sufficient size.

4. Only insecticides and rodenticides approved for use by the regulatory agency and/or registered with the U.S. Environmental Protection Agency shall be used for insect and rodent control.

NOTE: A convenient inspection form for milk plants, receiving stations and transfer stations, which summarizes the applicable sanitation requirements is found in Appendix M.

SECTION 8. ANIMAL HEALTH

(A) All milk for pasteurization shall be from herds which are located in a Modified Accredited Tuberculosis Area as determined by the U.S. Department of Agriculture. *Provided*, that herds located in an area that fails to maintain such accredited status shall have been accredited by said Department as tuberculosis free or shall have passed an annual tuberculosis test.

(B) All milk for pasteurization shall be from herds under a brucellosis eradication program which meets one of the following conditions:

1. Located in a Certified Brucellosis-Free Area as defined by the U.S. Department of Agriculture and enrolled in the testing program for such areas; or

2. Meet U.S. Department of Agriculture requirements for an individually certified herd; or

3. Participating in a milk ring testing program at least two times per year at approximately 180 day intervals and all herds with positive milk ring results shall have the entire herd blood tested within 30 days from the date of the laboratory ring tests; or

4. Have an individual blood agglutination test annually with an allowable maximum grace period not exceeding 2 months.

(C) Goat milk and sheep¹⁹ milk for pasteurization or ultra-pasteurization or aseptic processing shall be from a herd or flock which has passed an annual whole herd or flock tuberculosis and brucellosis test as recommended by the State veterinarian or regional USDA veterinarian

¹⁹ The implementation of the requirement for testing goat and sheep milk for Brucellosis was delayed until after the 2001 NCIMS Conference.

in charge (VIC) or from a herd or flock which has passed an initial whole herd Brucellosis test, followed only by testing replacement animals or any animals entering the milking group or sold as dairy animals.

(D) For diseases other than brucellosis and tuberculosis, the regulatory agency shall require such physical, chemical or bacteriological tests as it deems necessary. The diagnosis of other diseases in dairy animals shall be based upon the findings of a licensed and accredited²⁰ veterinarian or an accredited veterinarian in the employ of an official agency. Any diseased animal disclosed by such test(s) shall be disposed of as the regulatory agency directs.

(E) Records supporting the tests required in this section shall be available to the regulatory agency and be validated with the signature of a licensed and accredited veterinarian or an accredited veterinarian in the employ of an official agency.

PUBLIC-HEALTH REASON

The health of the animal is a very important consideration, because a number of diseases of cattle, including tuberculosis, brucellosis, Q-fever, salmonellosis, staphylococcal infection and streptococci infection, may be transmitted to man through the medium of milk. The organisms of most of these diseases may get into the milk either directly from the udder, or indirectly through infected body discharges which may drop, splash or be blown into the milk.

The great reduction in the incidence of bovine tuberculosis in man indicates that the practice of good sanitation in animal husbandry, the testing of dairy animals and removal of the reactors from the herds and

the pasteurization of milk, have been effective in the control of this disease. The reservoir of bovine tuberculosis still exists; however, constant vigilance against this disease must be continued by industry and health agencies.

ADMINISTRATIVE PROCEDURES

BOVINE TUBERCULOSIS: All tuberculin tests and retests shall be made, and any reactors disposed of, in accordance with the *Uniform Methods and Rules; Bovine Tuberculosis Eradication, Uniform Methods and Rules for Establishment and Maintenance of Tuberculosis-Free Accredited Herds of Cattle, Modified Accredited Areas and Areas Accredited Free of Bovine Tuberculosis in the Domestic Bovine*, as approved by the U. S. Department of Agriculture at the time of the adoption of this *Ordinance*. For tuberculosis test purposes, the herd is defined as all adult cattle 24 months of age and over, including any commingled beef animals. Dairy cattle less than 2 years of age and already milking, shall be included in the herd test. A letter or other official correspondence attesting to the accreditation status of the locality in which the herd is located, including the date of accreditation, or a certificate identifying the animals tested, the date of injection, the date of reading of the test and the results of the test signed by a U.S. Department of Agriculture accredited veterinarian, shall be evidence of compliance with the above requirements and shall be filed with the regulatory agency (See Appendix A).

BOVINE BRUCELLOSIS: All brucellosis tests, retests, disposal of reactors, vaccination of calves and certification of herds and areas shall be in accordance with *Brucellosis Eradication "Recommended Uniform Methods and Rules,"* as approved by the U.S. Department of Agriculture. All

²⁰ The term "accredited" in this section means accredited by the USDA APHIS Veterinary Services.

reactors disclosed on blood agglutination tests shall be separated immediately from the milking herd and the milk of these reactors shall not be used for human consumption.

A certificate identifying each animal, signed by the veterinarian and the director of the laboratory making the test, shall be filed as directed by the regulatory agency. *Provided*, that in the event the herd is subject to the milk ring test, the record shall be required to show only the date and results of such test. Within 30 days following the expiration of an official milk ring testing program, or in the case of a herd subject to annual blood tests, 13 months following the last annual blood tests, the regulatory agency shall notify the herd owner or operator of the necessity to comply with the brucellosis requirements. The failure of the herd owner or operator to comply with the brucellosis requirements within 30 days of written notice shall result in immediate suspension of the permit (See Appendix A).

SECTION 9. MILK AND MILK PRODUCTS WHICH MAY BE SOLD

From and after 12 months from the date on which this *Ordinance* is adopted, only Grade "A" pasteurized, ultra-pasteurized or aseptically processed milk and milk products²¹ shall be sold to the final consumer, to restaurants, soda fountains, grocery stores or similar establishments. *Provided*, that in an emergency, the sale of pasteurized milk and milk products which have not been graded, or the grade of which is unknown, may be authorized by the regulatory agency, in which case, such milk

²¹ Communities and/or States wishing to provide for the sale of certified pasteurized milk should include such product in this section.

and milk products shall be labeled "ungraded".

NOTE: Certified pasteurized milk is derived from certified raw milk which meets the latest requirements of the American Association of Medical Milk Commissions, Inc, 1824 North Hillhurst Avenue, Los Angeles, CA 90027.

SECTION 10. TRANSFERRING; DELIVERY CONTAINERS; COOLING

Except as permitted in this section, no milk producer, bulk milk hauler/sampler or distributor shall transfer milk or milk products from one container or milk tank truck to another on the street, in any vehicle, store or in any place except a milk plant, receiving station, transfer station or milkhouse especially used for that purpose. The dipping or ladling of milk or fluid milk products is prohibited.

It shall be unlawful to sell or offer for sale any pasteurized milk or milk product which has not been maintained at the temperature set forth in Section 7 of this *Ordinance*. If containers of pasteurized milk or milk products are stored in ice, the storage container shall be properly drained.

ADMINISTRATIVE PROCEDURES

TRANSFERRING: The dipping or ladling of milk and fluid milk products is expressly prohibited, except for immediate cooking purposes. Milk and milk product containers which have been filled and sealed at a milk plant shall be used for the delivery of milk or milk products. Caps, closures or labels shall not be removed or replaced during transportation.

BULK DISPENSERS: Bulk dispensers, approved by the regulatory agency,

shall satisfy the following sanitary design, construction and operation requirements:

1. All dispensers shall comply with the applicable requirements of Section 7 of this *Ordinance*.

2. Product-contact surfaces shall be inaccessible to manual contact, droplet infection, dust or flies, but the delivery orifice may be exempted from this requirement.

3. All parts of the dispensing device with which milk or milk products come into contact, including any measuring device, shall be thoroughly cleaned and sanitized at the milk plant. *Provided*, that dispensing valves which are applied to the dispenser subsequent to its delivery to the retail vendor may be cleaned and sanitized at such establishments.

4. The dispensing container shall be filled at the milk plant and shall be so sealed that it is impossible to withdraw any part of its contents, or to introduce any substance without breaking the seal(s).

5. The milk or milk products shall be thoroughly and automatically mixed with each dispensing operation, except for milk or milk products which remain homogeneous.

6. All cans shall be thoroughly cleaned and sanitized. Milk and milk products shall be kept at or below 7°C (45°F) at all times. The dispenser tube shall be integral with the dispensing container, shall be protected and shall be under adequate refrigeration during transportation and storage.

SECTION 11. MILK AND MILK PRODUCTS FROM POINTS BEYOND THE LIMITS OF ROUTINE INSPECTION

Milk and milk products from points beyond the limits of routine inspection of the ... of ..., or its jurisdiction, shall be sold in ...,²² or its jurisdiction, provided they are produced and pasteurized, ultra-pasteurized or aseptically processed under regulations which are substantially equivalent to this *Ordinance* and have been awarded an acceptable milk sanitation compliance and enforcement rating made, by a State Milk Sanitation Rating Officer certified by the Food and Drug Administration.

ADMINISTRATIVE PROCEDURE

The regulatory agency should accept, without their actual physical inspection, supplies of milk and milk products from an area or an individual shipper not under their routine inspection. *Provided*, that:

1. Milk and milk products upon arrival shall comply with bacteriological, chemical and temperature standards of Section 7. *Provided*, that direct shipped producer milk that is under the supervision of more than one regulatory agency may be exempt from the bacteriological requirement for commingled samples. However, the receiving regulatory agency shall have the right to use the individual producer samples to determine compliance with the bacteriological standards;

2. After receipt, pasteurized and ultra-pasteurized milk and milk products shall comply with Sections 2, 4 and 10;

²² Substitute proper jurisdiction here and in all similar places throughout the *Ordinance*.

NOTE: Raw and pasteurized milk and milk products beyond the limits of routine inspection shall be sampled as the regulatory agency requires.

3. The milk or milk products are produced and processed under regulations substantially equivalent to those of this *Ordinance*;

4. The supplies are under routine official supervision;

5. The supplies have been awarded, by the State Milk Sanitation Rating Officer certified by the Food and Drug Administration, a milk sanitation compliance and enforcement rating equal to that of the local supply or equal to 90 percent or higher; and

6. All ratings are made on the basis of procedures outlined in the *Methods of Making Sanitation Ratings of Milk Supplies*.

NOTE: Names of interstate milk shippers and their ratings, as reported by State milk rating agencies, are contained in *Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers*, issued semi-annually by the Food and Drug Administration for the information of interested persons. Copies of this list may be obtained from the State milk rating agency or from the Food and Drug Administration (HFS-626), 200 C Street, S.W., Washington, DC 20204.

7. The supplies have been awarded, a satisfactory listing, by the State Listing Officer standardized by the Food and Drug Administration, under the NCIMS HACCP Pilot Program. This provision will expire on December 31, 2001 unless extended by future Conference action.

SECTION 12. PLANS FOR CONSTRUCTION AND RE-CONSTRUCTION

Properly prepared plans for all milkhouses, milking barns, stables and parlors, milk plants, receiving stations and transfer stations regulated under this *Ordinance* which are hereafter constructed, reconstructed or extensively altered shall be submitted to the regulatory agency for written approval before work is begun.

SECTION 13. PERSONNEL HEALTH

No persons affected with any disease capable of being transmitted to others through the contamination of food shall work at a milk plant in any capacity which brings them into direct contact with finished products, such as pasteurized or aseptically processed milk or milk products, or which brings them into direct contact with associated pasteurized or aseptically processed milk product-contact surfaces.

ADMINISTRATIVE PROCEDURES

Milk plant operators who have received reports, under this section, from employees who have handled pasteurized milk, pasteurized milk products or associated product-contact surfaces shall immediately report these facts to the appropriate milk regulatory agency.

Dairy plant employees, or applicants to whom a conditional offer of employment has been made, shall be instructed by the dairy plant that the employee or applicant or applicants to whom a conditional offer of employment has been made is responsible to report to the dairy plant management, in a manner that allows the dairy plant to prevent the likelihood of disease transmission of diseases that are transmissible through

foods, if the employee or applicant to whom a conditional offer of employment has been made:

1. Is diagnosed with an illness due to Hepatitis A virus, Salmonella typhi, Shigella species, Norwalk and Norwalk-like Viruses, Staphylococcus aureus, Streptococcus pyogenes, Escherichia coli 0157:H7, enterohemorrhagic Escherichia coli, enterotoxigenic Escherichia coli, Campylobacter jejuni, Entamoeba histolytica, Giardia lamblia, Non-typhoidal Salmonella, Rotavirus, Taenia solium, Yersinia enterocolitica, Vibrio cholerae O1 or other infectious or communicable disease that has been declared by the Secretary of Health and Human Services to be transmissible to others through the handling of food, or has been clearly shown to be so based upon verifiable epidemiological data; or

2. Is exposed to, or suspected of causing, a confirmed foodborne disease outbreak of one of the diseases specified in number (1) above, including an outbreak at an event such as a family meal, church supper or ethnic festival because the employee or applicant to whom a conditional offer of employment has been made:

- a. Prepared food implicated in the outbreak, or
- b. Consumed food implicated in the outbreak, or
- c. Consumed food at the event prepared by a person who is infected or ill.

3. Lives in the same household as a person who attends or works in a day care center or school, similar institution experiencing a confirmed outbreak of one of the diseases specified in number (1) above.

Similarly, dairy plant employees shall be instructed by the dairy plant

management to report to the dairy plant management if the employee, or applicant to whom a conditional offer of employment has been made.

4. Has a symptom associated with acute gastrointestinal illness such as: abdominal cramps or discomfort, diarrhea, fever, loss of appetite for three or more days, vomiting, jaundice, or

5. Has a pustular lesion such as a boil or infected wound that is:

- a. On the hands, wrists or exposed portions of the arms, unless the lesion is covered by a durable, moisture proof, tight-fitting barrier, or
- b. On other parts of the body if the lesion is open or draining, unless the lesion is covered by a durable, moisture proof, tight-fitting barrier.

SECTION 14. PROCEDURE WHEN INFECTION OR HIGH RISK OF INFECTION IS DISCOVERED

When a person who may have handled pasteurized or aseptically processed milk or milk products or pasteurized or aseptically processed milk product-contact surfaces meets one or more of the conditions specified in the administrative procedures of Section 13, the regulatory agency is authorized to require any or all of the following measures.

The immediate restricting of that person from duties which require handling finished product, such as pasteurized milk or milk products, or the handling of related product-contact surfaces. This restriction may be lifted after an appropriate medical clearance or cessation of symptoms or both, according to the following criteria:

Table 5. Removal of Restrictions When Infection or High Risk of Infection is Discovered

Health Status	Removing Restrictions
a. Is diagnosed with an illness due to Hepatitis A virus, <u>Salmonella typhi</u> , <u>Shigella</u> species, Norwalk and Norwalk-like Viruses, <u>Staphylococcus aureus</u> , <u>Streptococcus pyogenes</u> , <u>Escherichia coli</u> 0157:H7, enterohemorrhagic <u>Escherichia coli</u> , enterotoxigenic <u>Escherichia coli</u> , <u>Campylobacter jejuni</u> , <u>Entamoeba histolytica</u> , <u>Giardia lamblia</u> , Non-typhoidal <u>Salmonella</u> , Rotavirus, <u>Taenia solium</u> , <u>Yersinia enterocolitica</u> , <u>Vibrio cholerae</u> O1 or other infectious or communicable disease that has been declared by the Secretary of Health and Human Services to be transmissible to others through the handling of food or has been clearly shown to be so based upon verifiable epidemiological data.	Restrictions lifted by medical clearance.
b. Meeting a high risk scenario as specified in Section 13 (2 or 3) and/or experiencing symptoms in Section 13 (4 or, 5).	Restrictions lifted when symptoms cease or medical documentation is provided that infection does not exist.
c. Asymptomatic, but stools positive for <u>Salmonella typhi</u> , <u>Shigella</u> or <u>Escherichia coli</u> 0157:H7.	Restrictions lifted by medical clearance.
d. Past illness from <u>Salmonella typhi</u> , <u>Shigella</u> , <u>Escherichia coli</u> 0157:H7 or other human pathogens for which humans have been determined to be carriers.	Restrictions lifted by medical clearance.
e. In the case of diagnosed or suspected Hepatitis A, onset of jaundice within the last seven (7) days.	Restrictions lifted by medical clearance.
f. In the case of diagnosed or suspected Hepatitis A, onset of jaundice occurred more than seven (7) days ago.	Restrictions lifted by medical clearance or jaundice ceases.

1. The immediate exclusion of the affected dairy products from distribution and use when medically appropriate (i.e., a medical evaluation of the sequence of events indicates that contamination of product may have occurred).

2. The immediate requesting of medical and bacteriological examination of the person at risk. (NOTE: Persons at risk who decline to be examined may be reassigned to duties where they will not be required to handle finished products, such as pasteurized or aseptically processed milk or pasteurized or aseptically processed milk products and associated product-contact surfaces).

SECTION 15. ENFORCEMENT

This Ordinance shall be enforced by the regulatory agency in accordance with the *Grade "A" Pasteurized Milk Ordinance with Administrative Procedures-1978 Recommendations of the United States Public Health Service/Food and Drug Administration*, 1999 Revision. A certified copy²³ of which shall be on file at the ... clerk's office. Where the mandatory compliance with provisions of the appendixes is specified, such provisions shall be deemed a requirement of the *Ordinance*.

SECTION 16. PENALTY

Any person who shall violate any of the provisions of this *Ordinance* shall be guilty of a misdemeanor and upon conviction thereof shall be punished by a fine of

not more than \$... and/or such persons may be enjoined from continuing such violation(s). Each day upon which such a violation(s) occurs shall constitute a separate violation.

SECTION 17. REPEAL AND DATE OF EFFECT

All ordinances and parts of ordinances in conflict with this *Ordinance* shall be repealed 12 months after the adoption of this *Ordinance*, at which time this *Ordinance* shall be in full force and effect, as provided by law.

SECTION 18. SEPARABILITY CLAUSE

Should any section, paragraph, sentence, clause or phrase of this *Ordinance* be declared unconstitutional or invalid for any reason, the remainder of this *Ordinance* shall not be affected thereby.

²³ A certified copy may be secured from the Food and Drug Administration, HFS-626, 200 "C" Street, S.W., Washington DC 20204.

